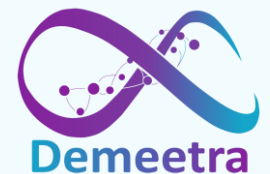


From CHO Cell Line to the Clinic:

Decisions That Will Make or Break Your Biologics Program

Magnus Gustafsson, CCO NorthX Biologics | Jack Crawford, CEO Demeetra



Where CHO comes from and Why CleanCut™ GS CHO



CHO Origin

Puck & Kao · 1957



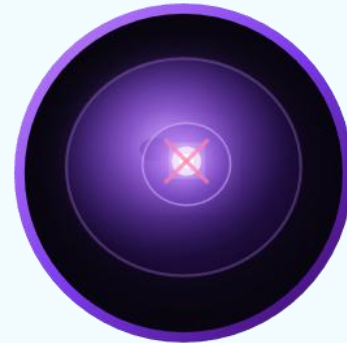
CHO-DG44

DHFR^{-/-} · MTX selection



CHO-K1 Suspension

Industry standard host



Single GS KO

Chr.5 KO · leakage risk



CleanCut™ GS CHO

Chr.5 + Chr.1 · Cas-CLOVER

- ✓ ~87% of mAbs, bsAbs & Fc-fusions
- ✓ Human compatible glycosylation
- ✓ 40+ years regulatory precedent
- ✓ Scalability

- ✗ Selection creates instability
- ✗ Lower cell density

- ✓ Top foundational CHO cell
- ✗ Lacks robust selection
- ✗ MSX damages cells

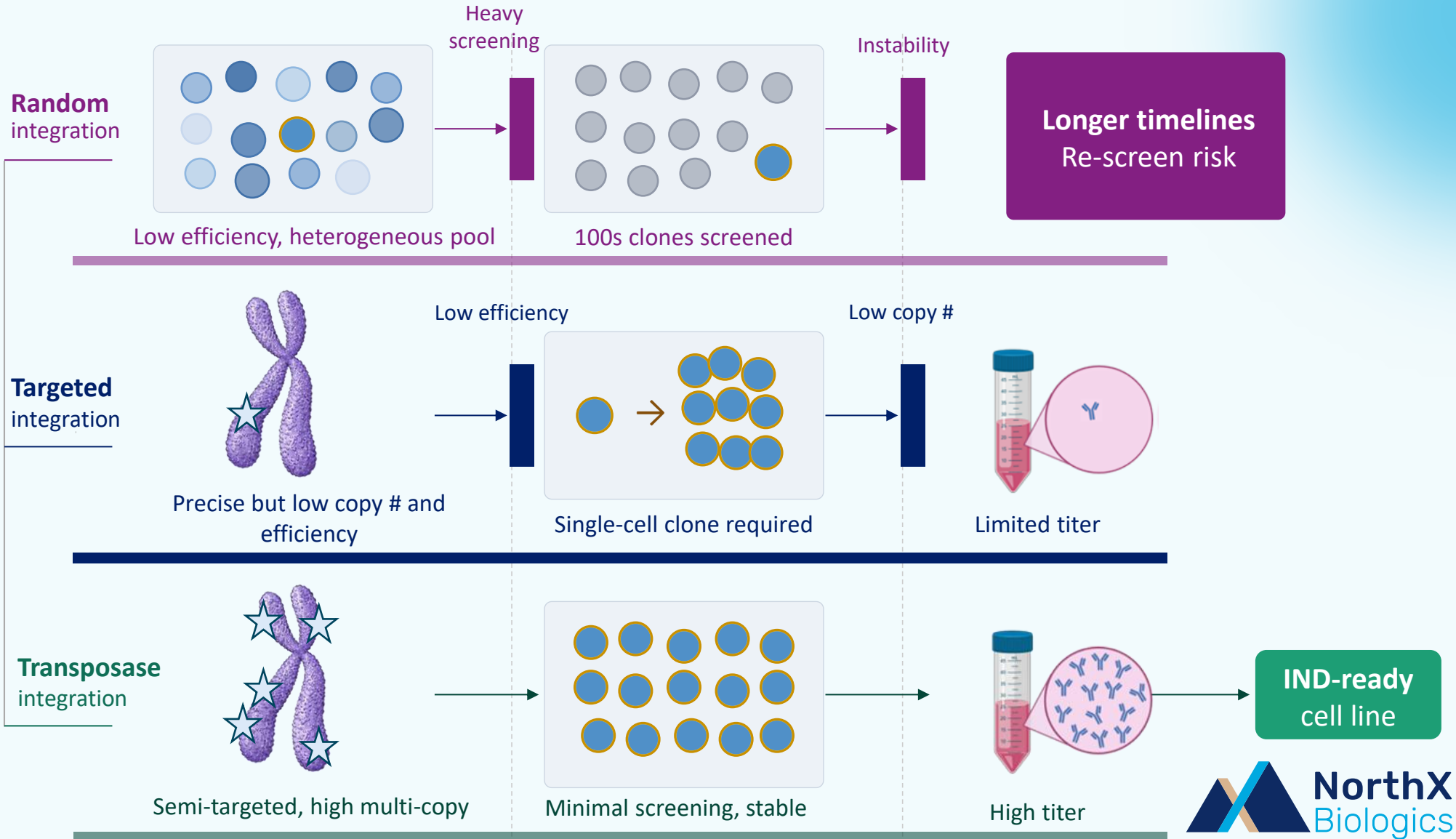
- ✗ Selection leakage & timeline
- ✗ Licensing drag

- ✓ Faster more robust selection
- ✓ License free

Three integration approaches

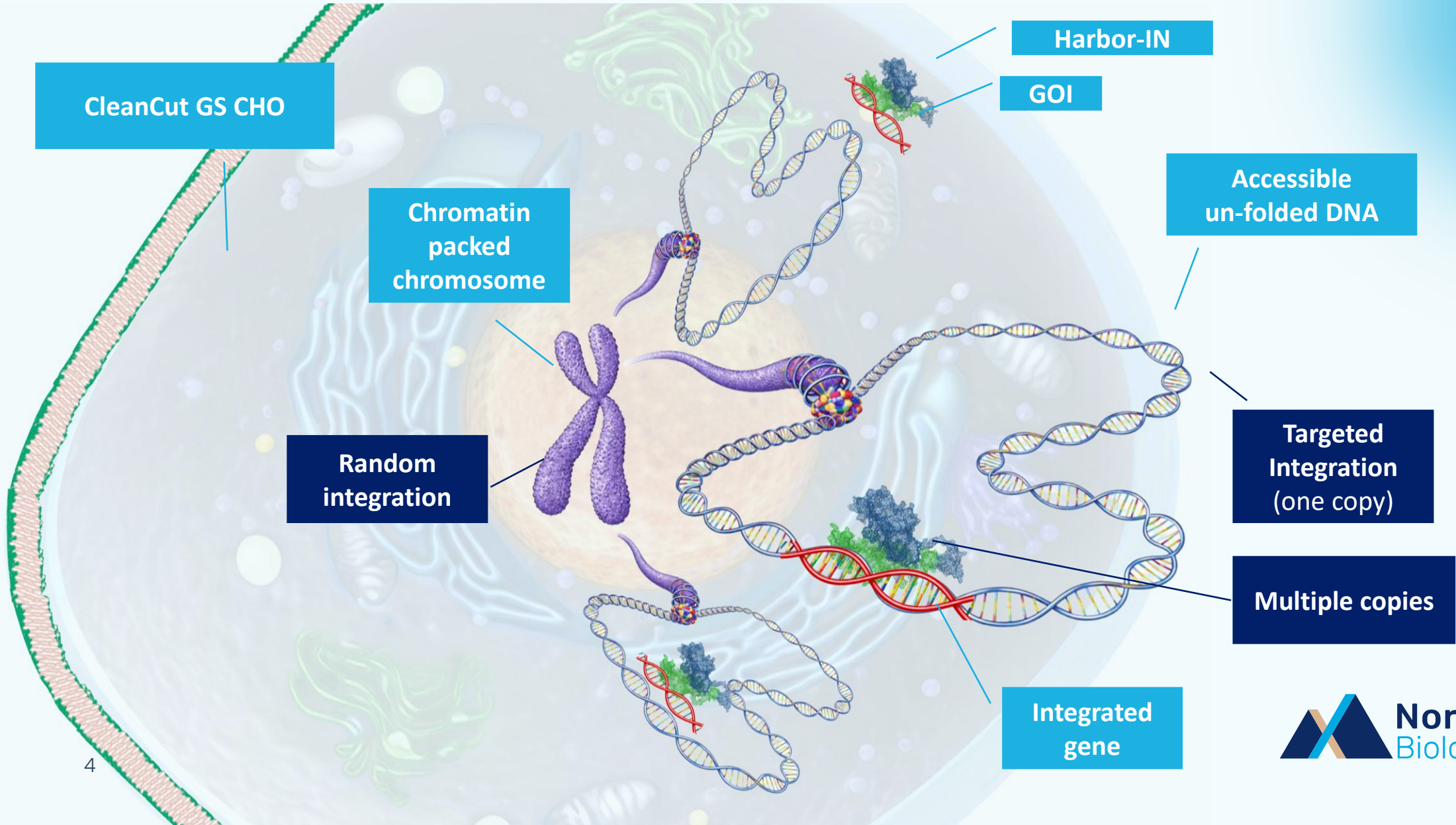
Why the method determines your timeline and titer

Lead Candidate
Gene in hand

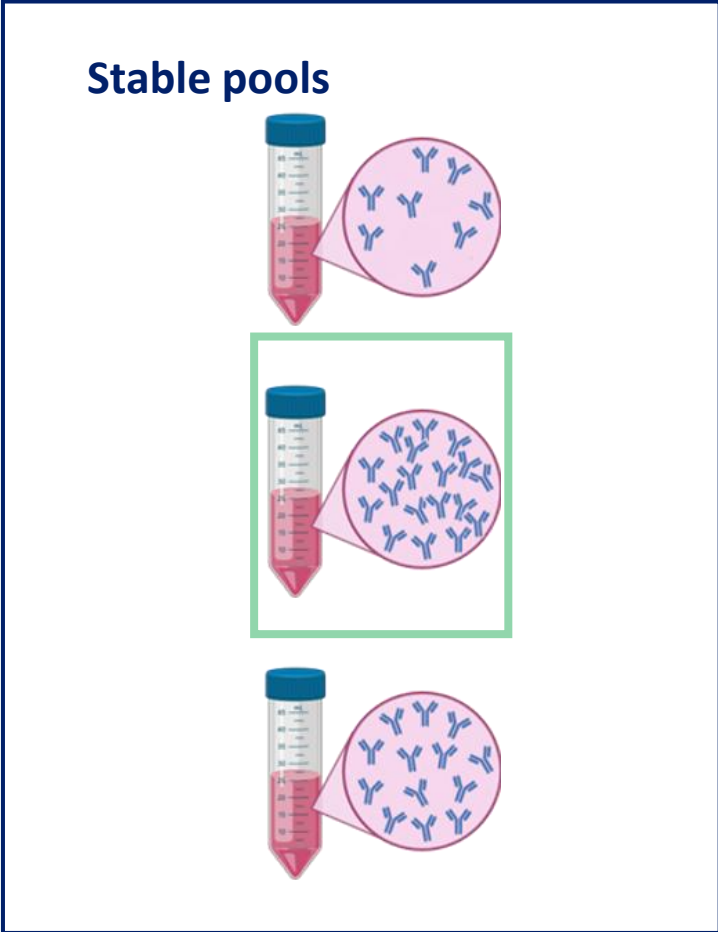
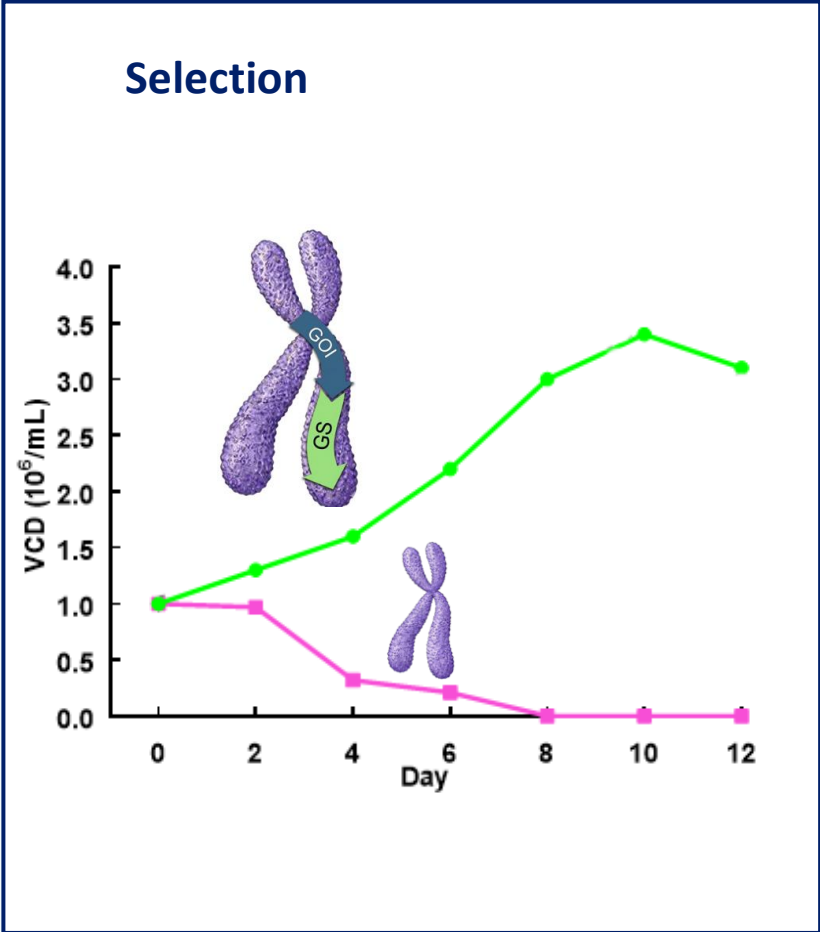
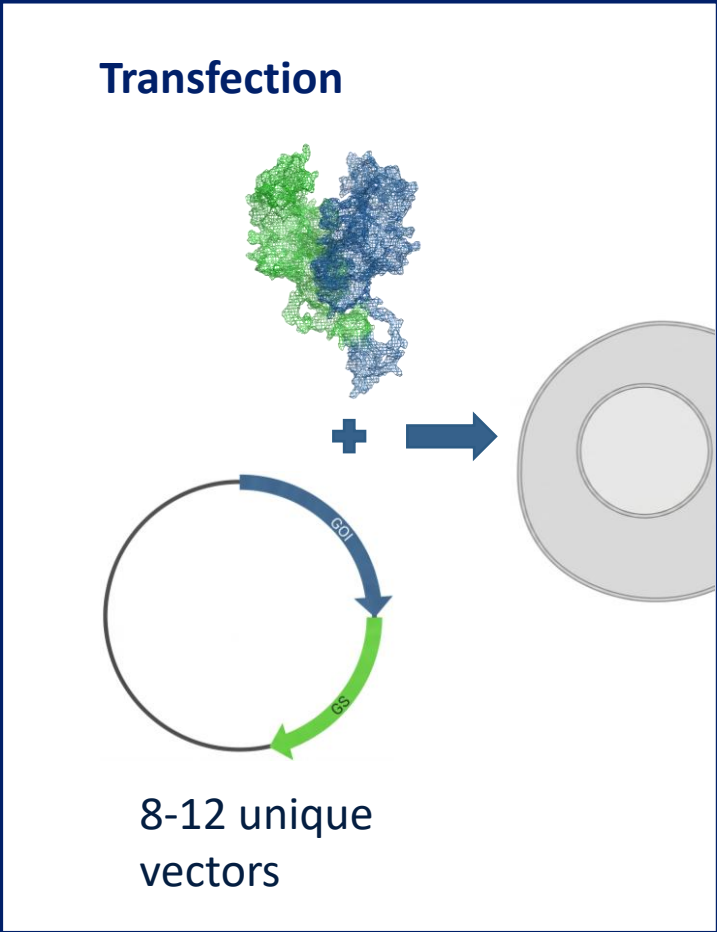


The Harbor-IN Integration Mechanism

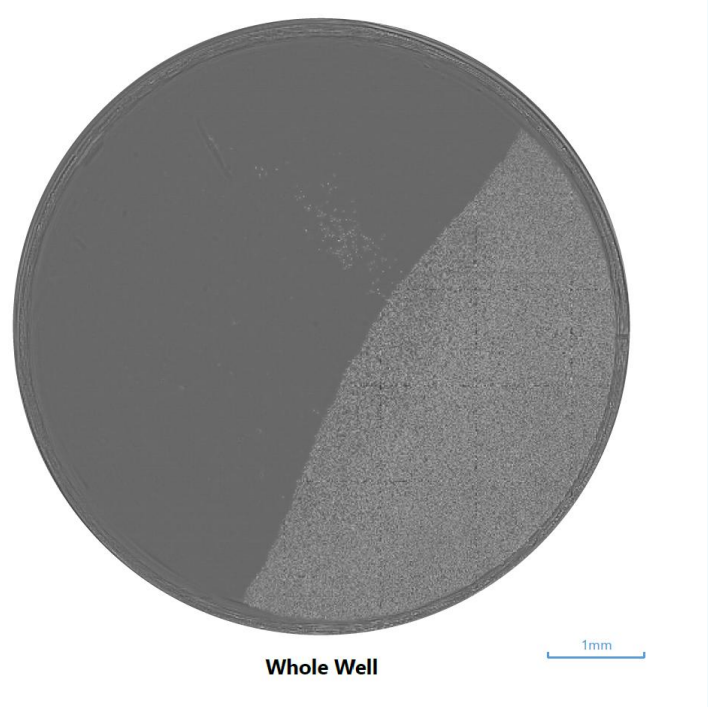
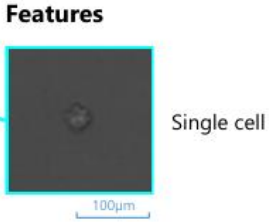
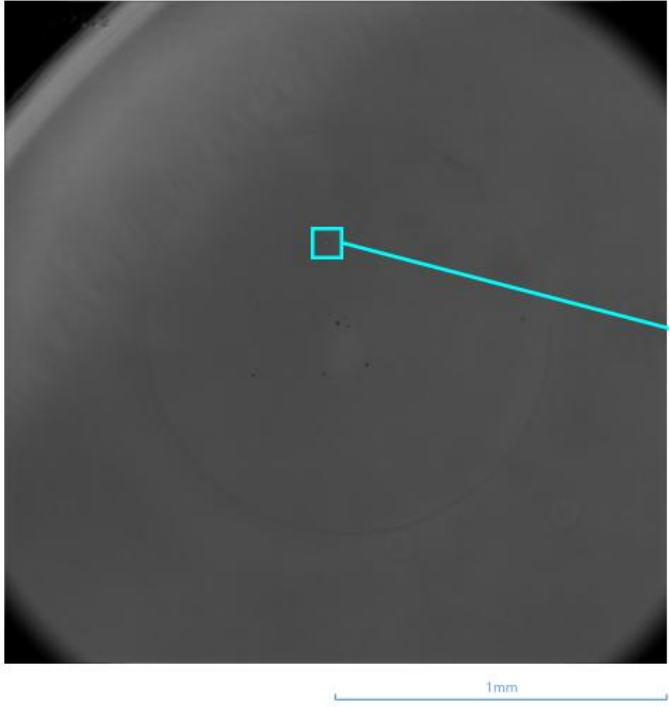
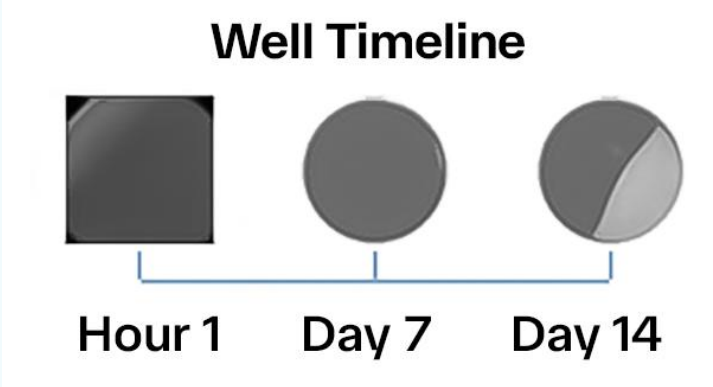
Compared to other integration approaches



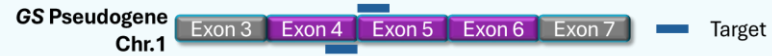
Step 1: Rapid, Robust Pool Generation



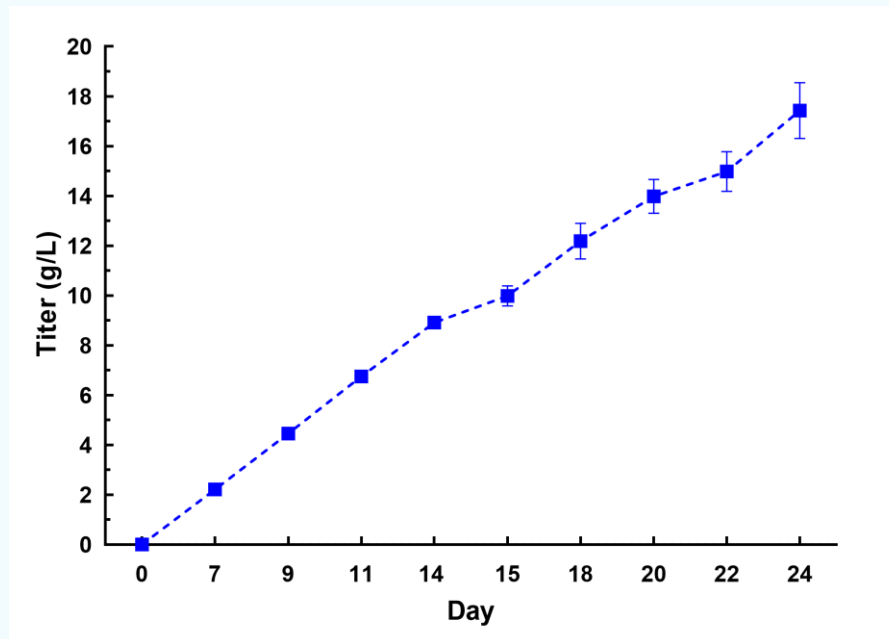
Step 2: Isolating and Selecting Top-Performing Clones



Demeetra Cell Line Development Platform



Antibody Pool Titer 18 g/L



1 Used by 20+ Companies

2 Media is of Animal-free Origin
Grows in single cells in suspension

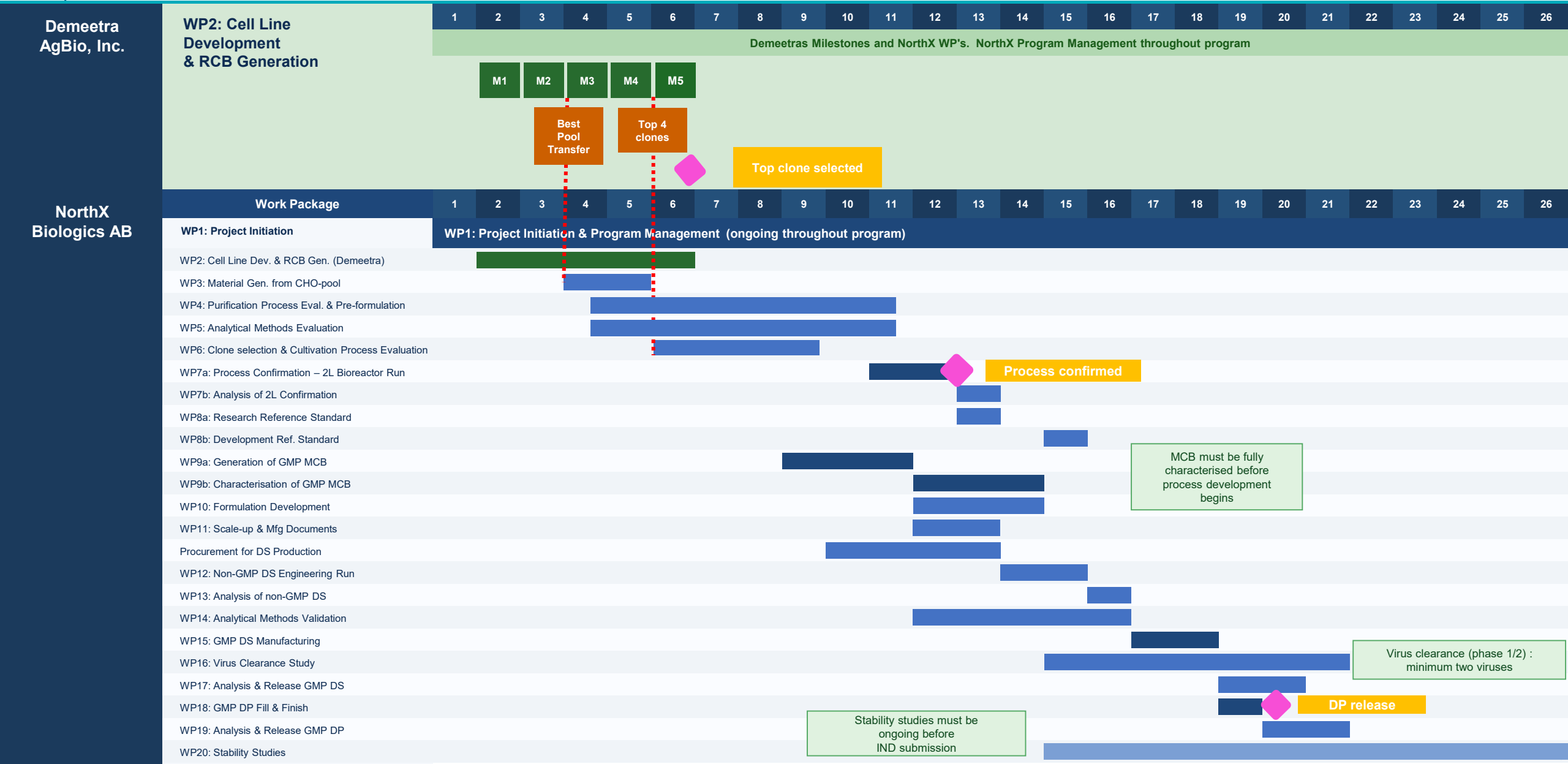
3 Full History Report &
Traceability

4 Viral-Panel Tested

5 Royalty-Free

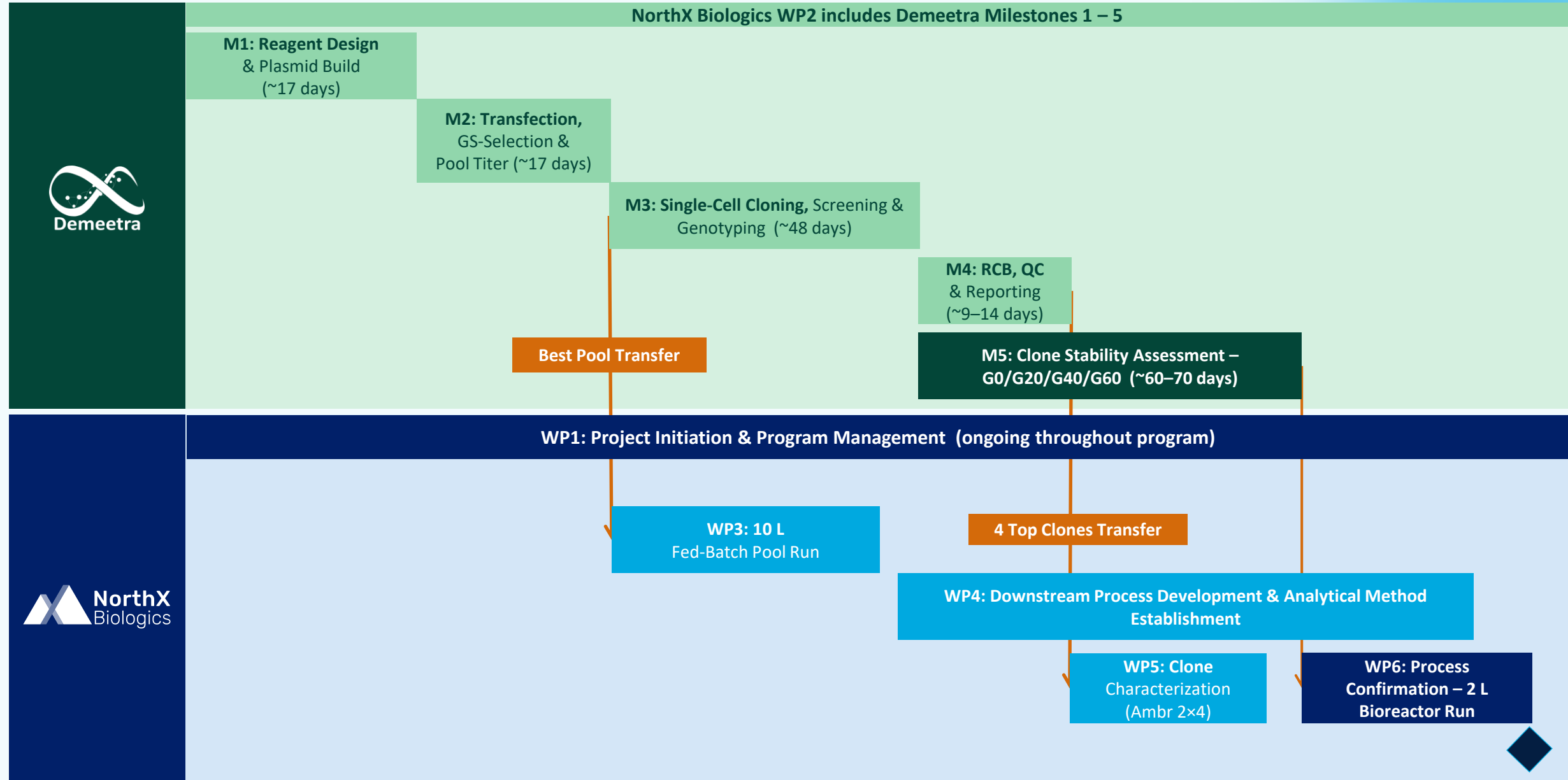
Generic mAb CHO Program – Full mAb

Project Timeline & Workflow Overview



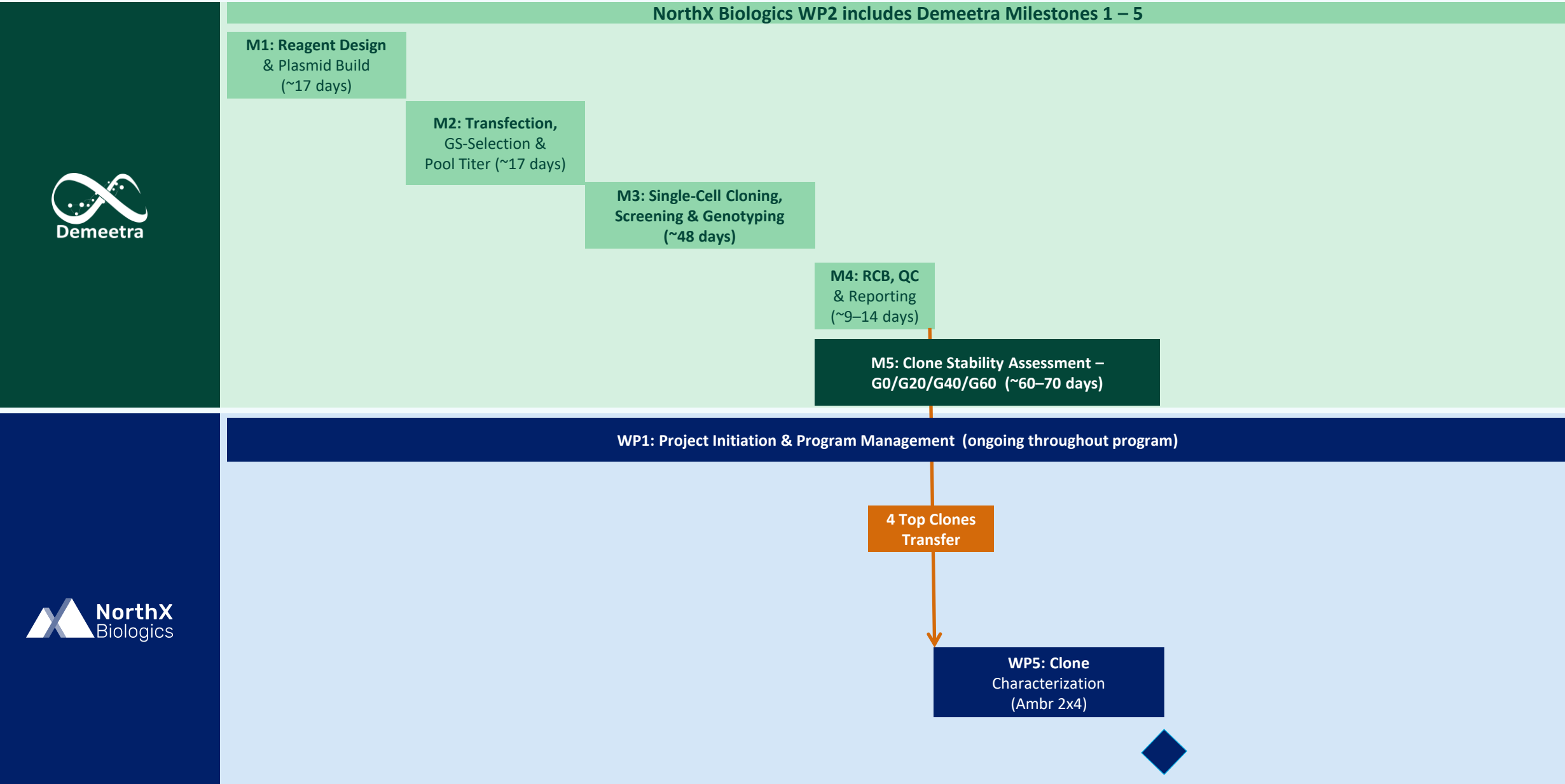
Generic mAb Program – CLD & process establishment

Project Timeline & Workflow Overview



Generic mAb Program – CLD

Project Timeline & Workflow Overview



Analytical Overview – standard mAb offering

Category	Attribute	Method	Release	IPCs	Stab.
Identity	Capillary Isoelectric Focusing	cIEF	DS/DP		
	Binding Activity	ELISA	DS/DP		
Purity	Monomer Purity	SE-HPLC	DS/DP		DS/DP
	Fragmentation/aggregation	CE-SDS-LIF (red/non-red.)	DS/DP		DS/DP
	Charge Heterogeneity	cIEF	DS/DP		DS/DP
	Residual Host Cell DNA	qPCR	DS		
	Residual Host Cell Proteins	ELISA	DS		
	Residual Ligand Protein A	ELISA	DS		
Potency	Binding Activity	ELISA	DS/DP		DS/DP
Quantity	Protein Concentration	A280	DS/DP		DS/DP
Safety	Endotoxin	Ph. Eur. 2.6.14 (D)	DS/DP	X	DS/DP
	Bioburden	TAMC/TYMC	DS	X	DS
	Sterility	Ph. Eur. 2.6.1	DP		DP
	CCIT	Pressure Decay	DP		
	Sub-visible particles	USP <787>	DP		DP
	Mycoplasma	Various		X	
Physiochem.	pH	Ph. Eur. 2.2.3	DS/DP	X	DS/DP
	Osmolality	Ph. Eur. 2.2.35/USP	DS/DP		DS/DP
Other	Color and Clarity	Ph. Eur. 2.2.1/2.2.2	DS/DP		DS/DP
	Appearance, Visual	Ph. Eur. 2.9.20	DS/DP		DS/DP
	Particles (visible)	Ph. Eur. 2.9.20	DP		DS/DP
	Extractable volume	USP <697>	DP		

USP IPCs: VCD, viability, metabolites and gases, mycoplasma, mycoplasma stasis, pH, titer, bioburden, MMV, TEM and 28-day in vitro. DSP IPCs: pH, titer, bioburden, A280, endotoxin, conductivity, and pO2.

Questions?

Protect Your Asset at Every Stage

WHAT DEMEETRA + NORTHX OFFERS

One continuous workflow — no reset

Royalty-free through commercialization

GMP-aligned from day one

One MSA. One partnership. Gene → Clinical material, with your timeline, margin, and asset value intact.