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COGS by Design: a systems approach to achieving commercially viable cellular therapy products

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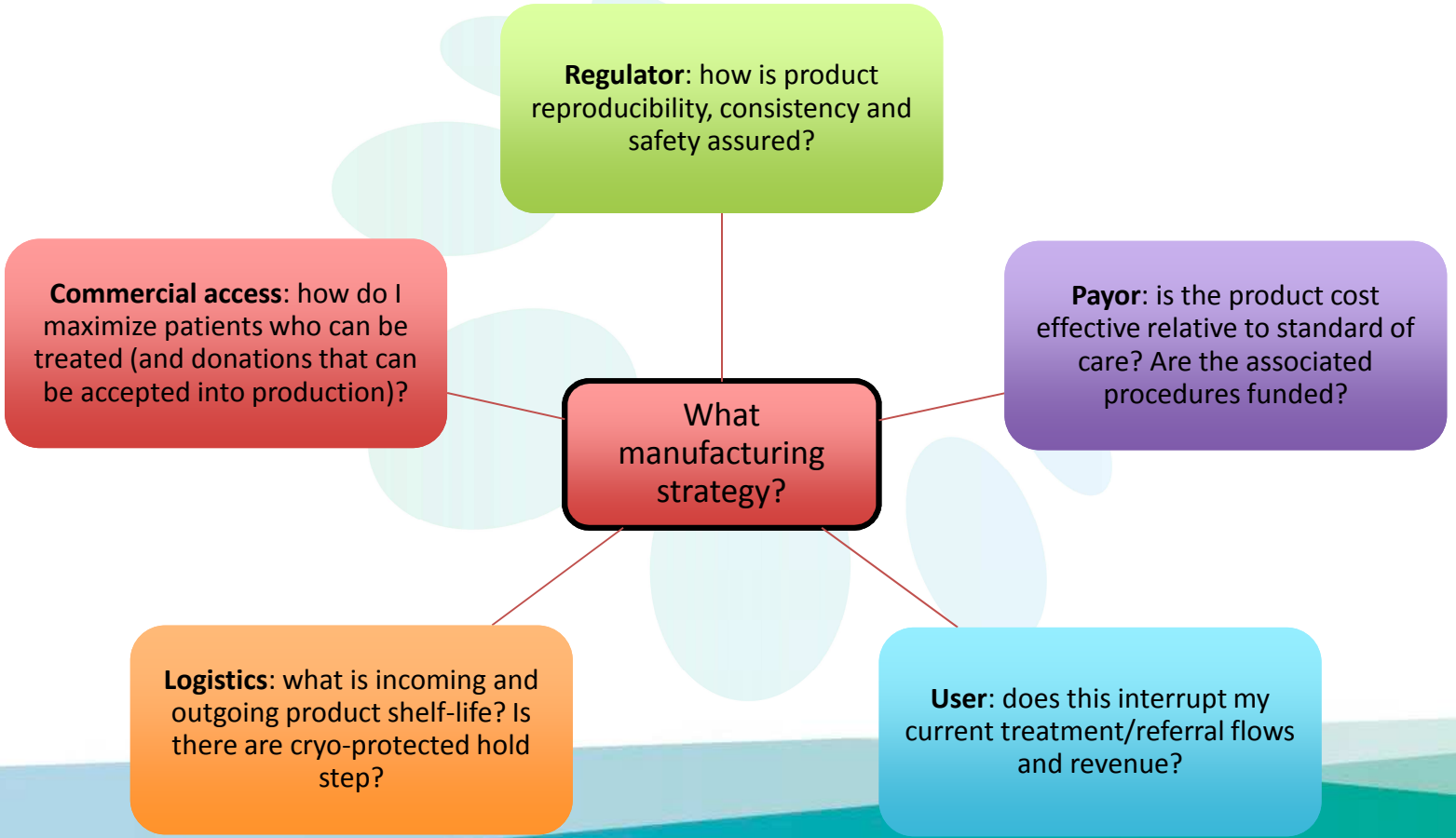
Summary

- Identifying the total “needle-to-needle” cost of therapy to healthcare systems against its healthcare must be the starting point for intelligent product and process development (COGS by design)
- Understanding cost drivers, including the costs of quality, early in process development maximizes opportunities to achieve viable product costs
- Multiple process design and deployment choices are required to optimise COGS and the choices are different for autologous and allogeneic therapy

Target product profile (and hence COGS target and manufacturing strategy) is influenced by multiple stakeholders other than the scientist



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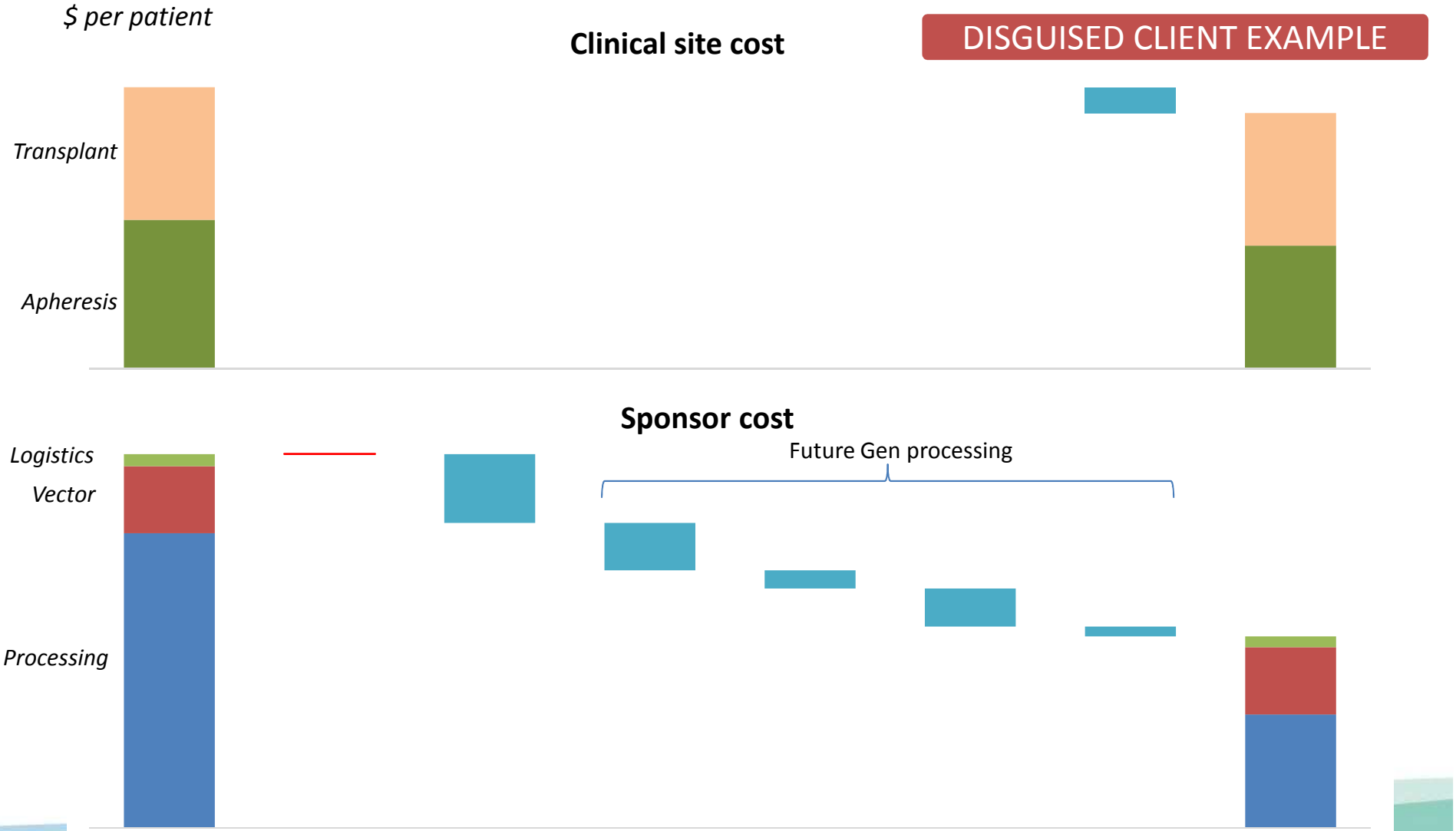
COGS improvement opportunity summary

$ per patient

DISGUISED CLIENT EXAMPLE



Source: Disguised client example

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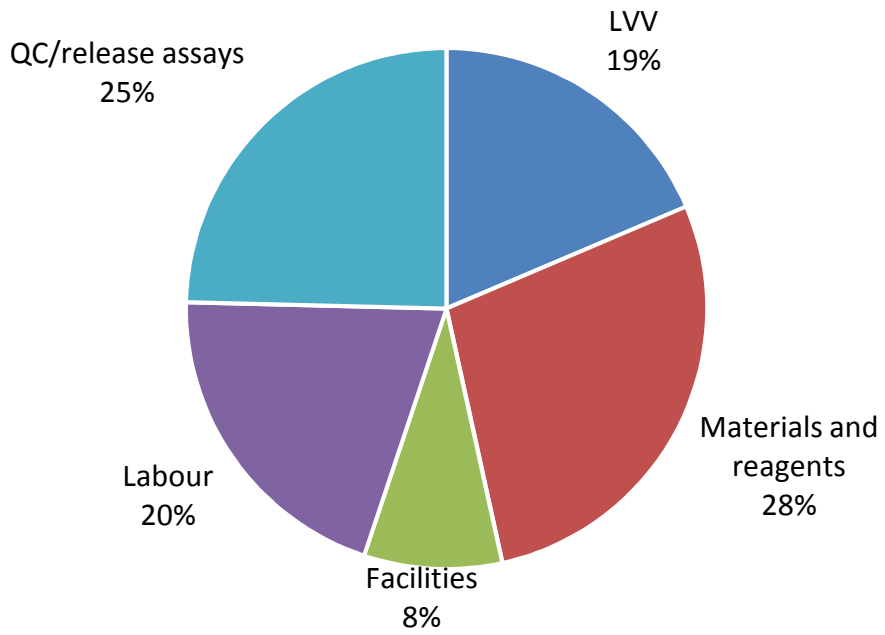
Sponsor's COGS drivers: multiple levers must be pulled

Manufacturing costs: manual gene modified process at scale

100% = $50-90k



Achieving a notional target COGS <$30k requires 65% reduction

Release testing, reagents and consumables, and facility costs contribute approximately equally to total product costs

Cost reduction solutions must address all three areas

Source: Disguised client example

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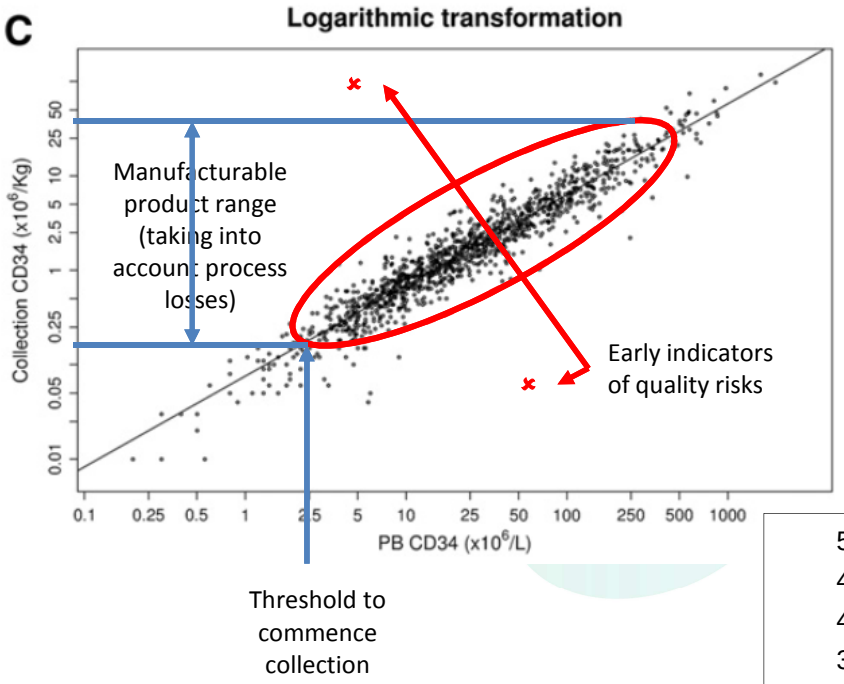
Apheresis variability drives manufacturing cost complexity

Collection algorithms



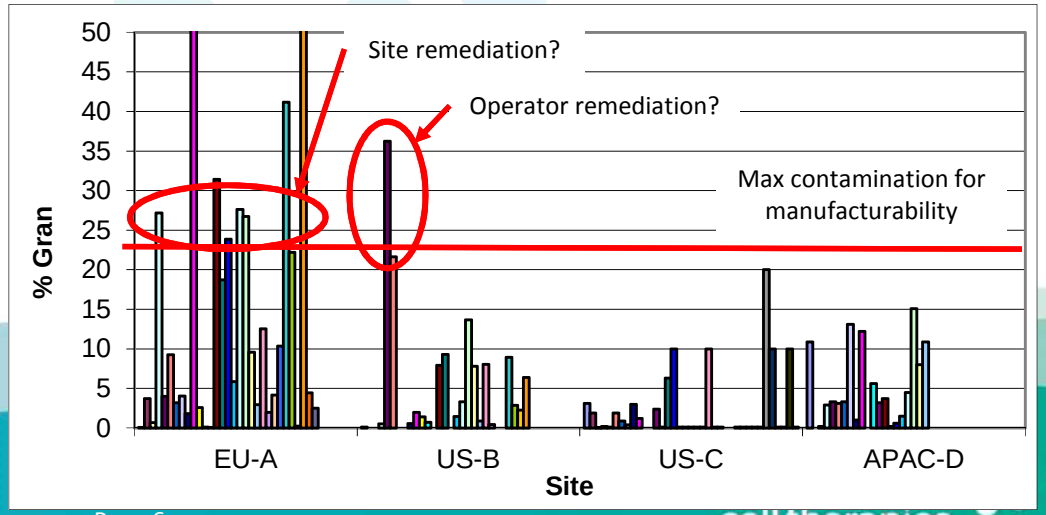
Key attributes

T-cells: collection efficiency then composition

CD34+: collection efficiency then composition

Monocytes for DC therapy: composition then collection efficiency

Site monitoring and benchmarking



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Start early: avoid locking in costly processes

DISGUISED CLIENT EXAMPLE

Stage	Fold-expansion	Lab scale (static)		Optimisation 1		Target	
		Density (rel value)	Volume (L)	Density (rel value)	Volume (L)	Density (rel value)	Volume (L)
A	20	1	0.025	1	0.03	10	0.05
B	20	1	0.5	1	0.6	10	1
C	20	1	10	1	12.5	20	10
D	10	1	200	33	7.6	200	20
Final density		10		264		2000	20
Doses		1		1		20	
Cost/dose (reagents)		$176k		$22k		$3k	
Drivers		Stage D = 92% One growth factor = 57%		Stage C = 72%		All stages ~25%	

Stage D feasibility
Stirred culture
Halve growth factor

PD goals
Perfusion culture
Recombinant growth factor

Overarching goals for commercial manufacturing

Quality	• Maximize product AND process consistency, reliability and reproducibility
Scalability	• Minimize process changes at each level of scale-up/out • Maximize capital efficiency (modularity, staged investment, multi-use facilities and technologies)
Sustainability	• Ability to drive continuous improvement • Anticipate COMPARABILITY
COGS	• Minimize COGS (total cost per patient across supply chain)

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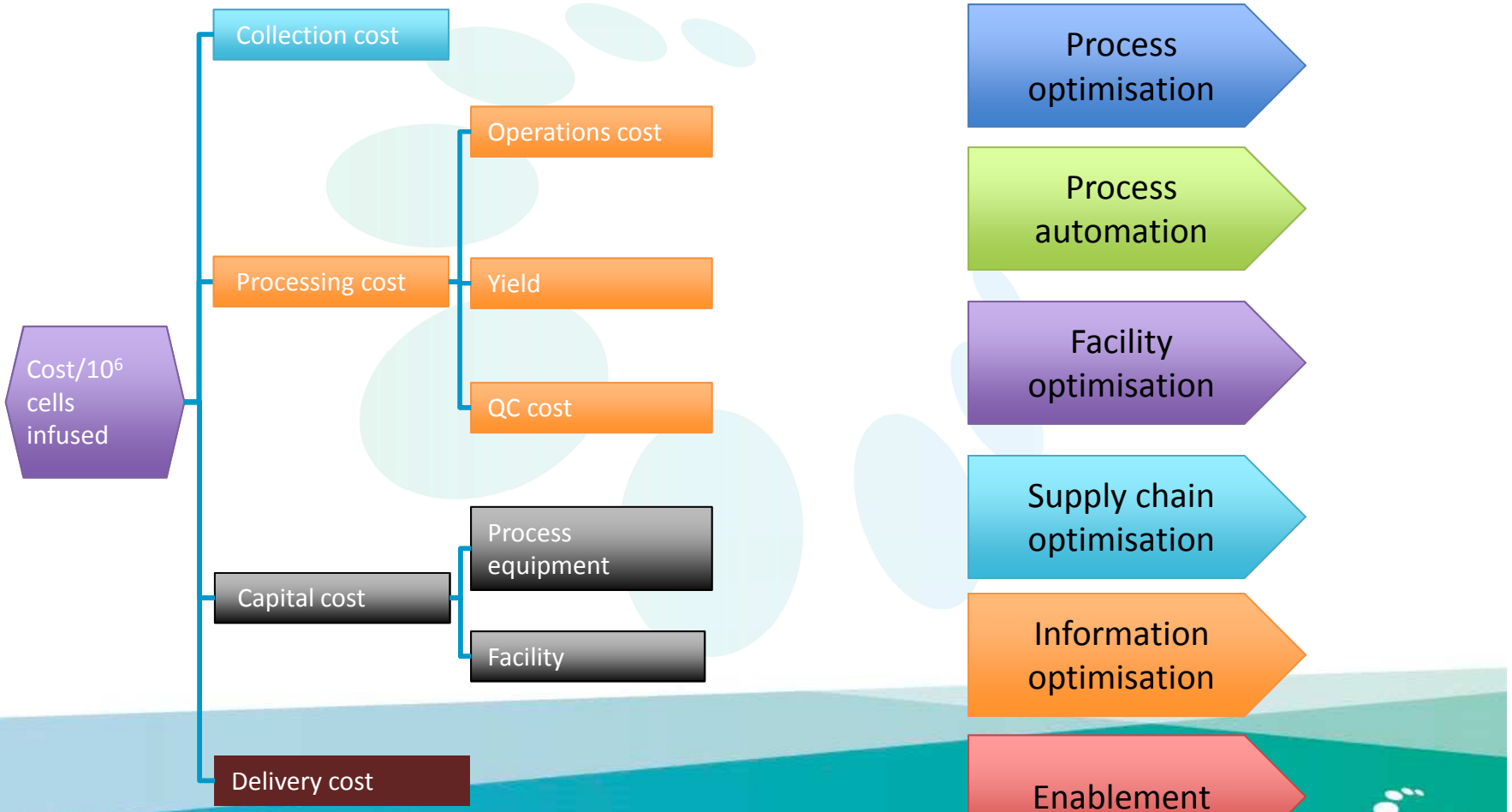
“Autologous production for the future” requires a systems approach



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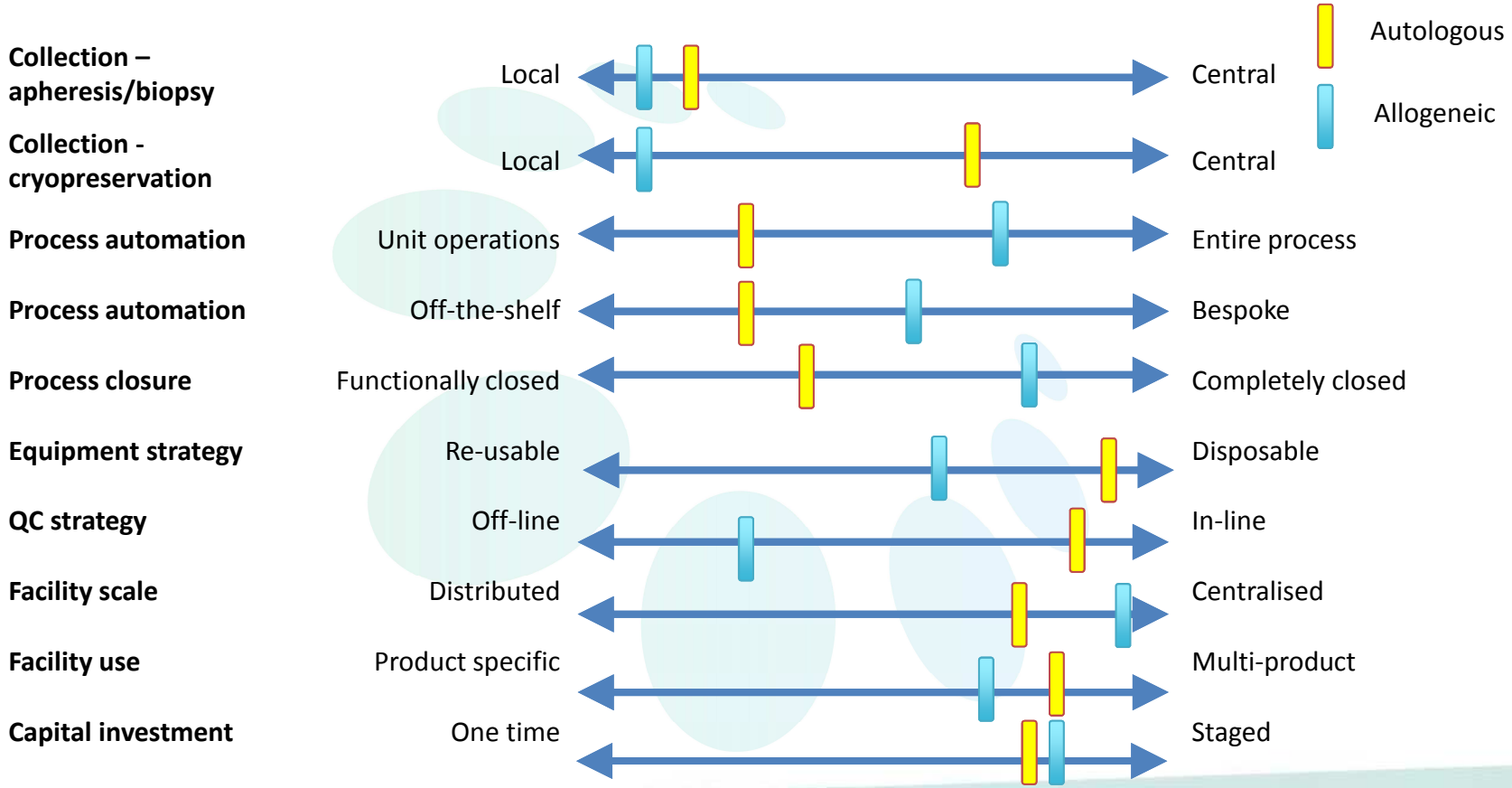
Key design choices/philosophy



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thank you

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