



cell therapies

# Managing apheresis as source of cellular therapy starting material

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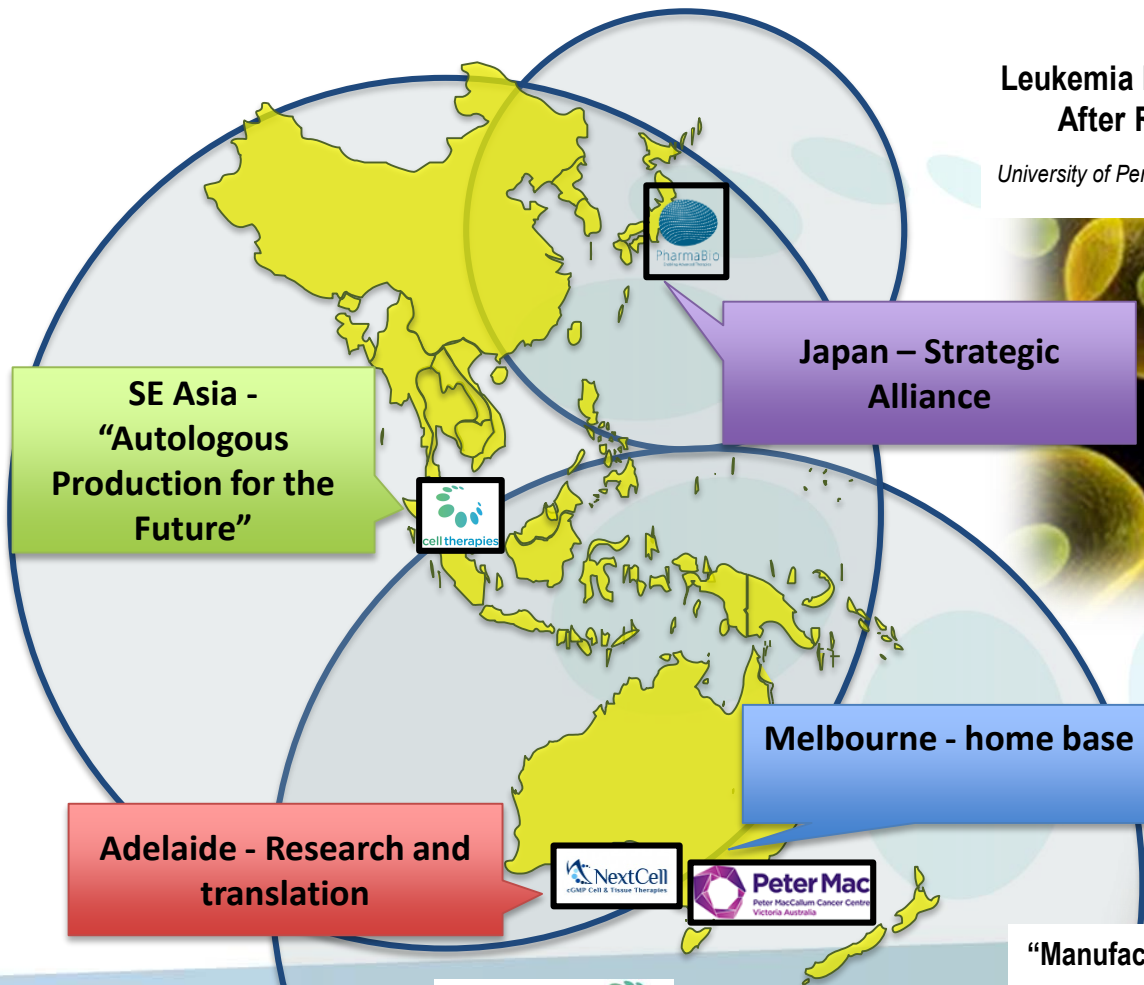
Cell & Gene Therapy World, Washington DC, 2016

# Managing apheresis as a source of cellular therapy starting material: abstract

*The starting cells are the most critical starting material for any cellular therapy ... and the most variable. There is inherent tension between manufacturing (minimal variability) and clinical/commercial (minimal clinical site disruption) on how this variability is managed. Resolving this tension favourably fundamentally impacts commercial and clinical viability of autologous products in particular.*

*Using apheresis collection as an example, the potential to standardise collection management without breaking the bank or turning away patients will be described. Formally developing the collection process and deploying through centres of excellence is encouraged.*

# CTPL vision: essential enabler of clinical and commercial scale cellular therapy manufacturing and deployment in Asia Pacific



## Leukemia Patients Remain in Remission More Than Two Years After Receiving Genetically Engineered T Cell Therapy

University of Pennsylvania Researchers Report on Results of Trial in 12 Patients, Including Two Children



“Manufacturing will be a competitive advantage”  
Jason Kolbert

**MAXIM**  
GROUP



Reach of managed apheresis/tissue  
collection site network and  
commercialisation capability



# Quality management of apheresis collections is a major pain point for cellular therapies

## Manufacturing wants ...

Quality oversight (regulatory requirement)

Maximum data for procedure/process optimisation

Tight incoming product spec – low variation

## Clinical/commercial wants ...

Latest possible “intent to treat”

Minimal imposition on sites

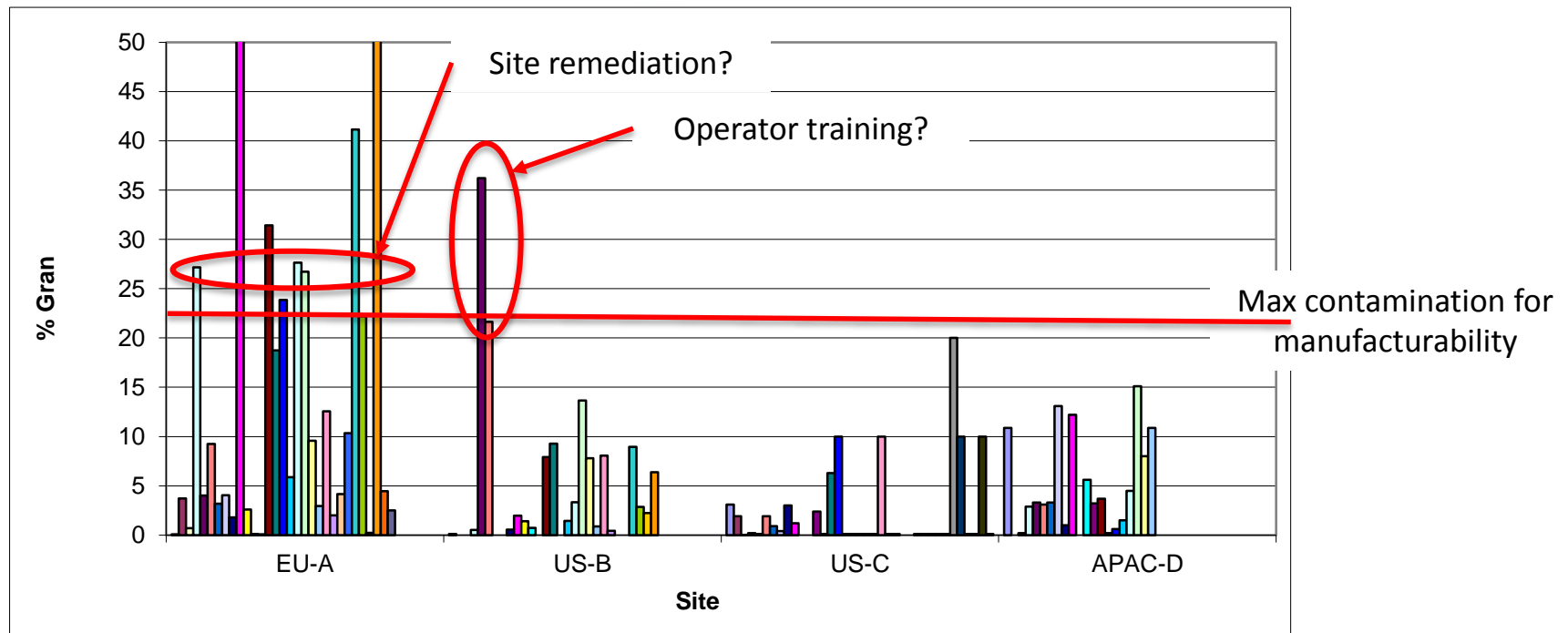
Wide product spec/ maximum patient access

**Apheresis product: the most critical and hardest to control starting material for cellular therapy**

## Multiple sources of variability and risk

- Donor, operator, collection platform and analytic platform variability
- Cryopreservation and thawing
- Identity tracking and serology
- Minimum manufacturability requirements unknown/poorly defined
- Manufacturing process variability to accommodate variable starting material
- Local regulatory oversight requirements
- Just in time production scheduling vulnerable to collection failure

# Collection site monitoring and benchmarking



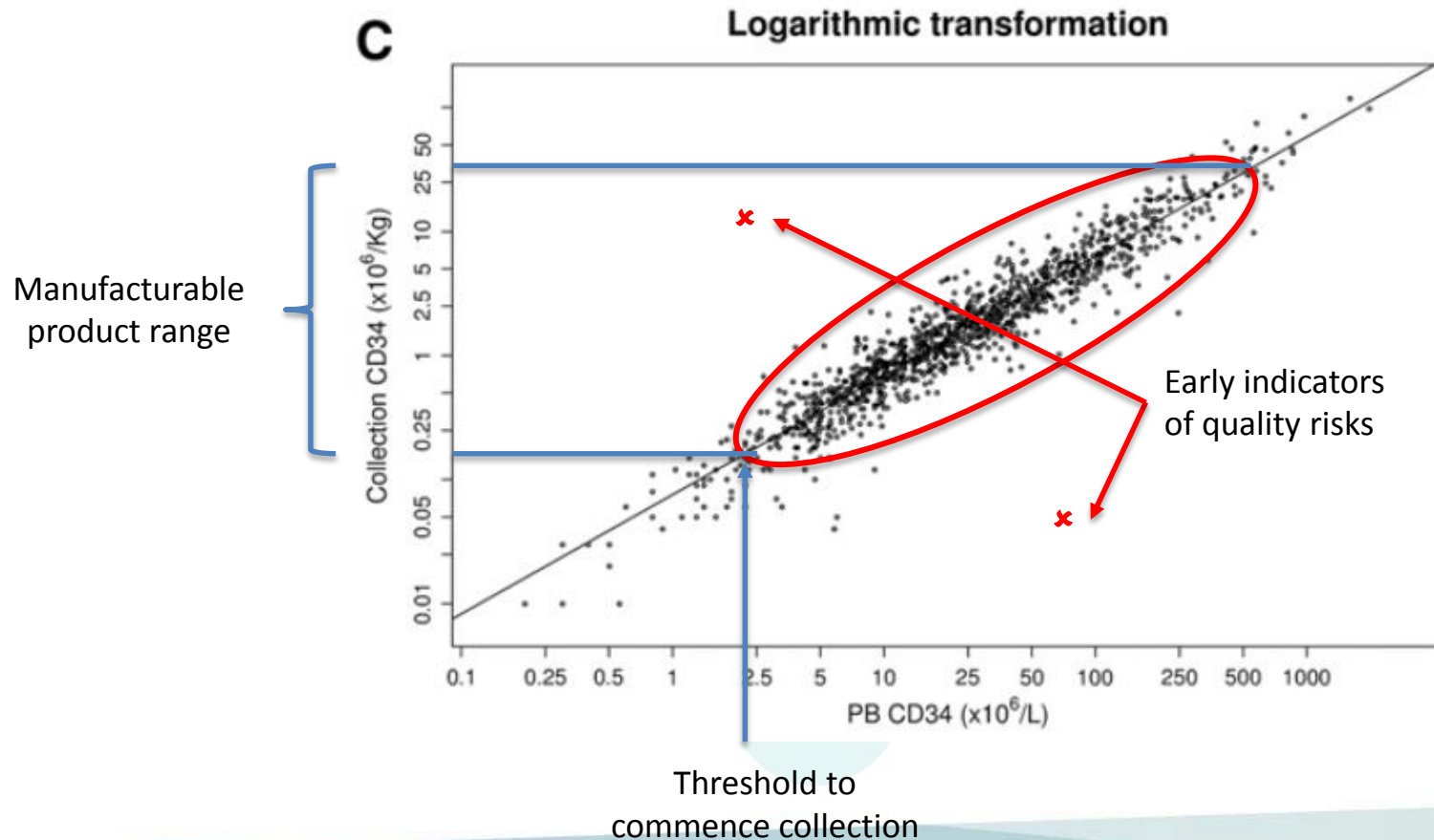
## Key collection quality attributes

*T-cells*: collection efficiency then composition

*CD34+*: collection efficiency then composition

*Monocytes for DC therapy*: composition then collection efficiency

# Apheresis process development: collection algorithms



# CTPL's apheresis service line provides scalable control of critical starting materials

## Apheresis development

- CQA (integrate cell processing AND clinical site/patient processes)
- Collection protocols; acceptance criteria
- Comparability

## Apheresis SOP's

- SOP's, manuals and data protection
- Process specific customization
- Quality/technical agreements

## Site selection

- Site screening criteria
- Audits and gap analysis

## Site establishment

- Customise/localise SOP's
- Training
- Quality agreement
- Supervise initial collection(s)

## Collection and logistics monitoring

- Referral, scheduling, shipping procedures
- Remote deviations management and Helpdesk
- Performance analysis
- Remediation

**Staged roll-out via centres of excellence: concentrate volume and experience**

**Centres may not be treatment sites?**

**Cryo-preservation hubs?**

**Standardised analytics?**

thank you



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