

DEVELOPMENT OF PROCESSING PLATFORMS FOR THE INDUSTRIAL MANUFACTURE OF PSC-DERIVED CELL THERAPY PRODUCTS: CELL EXPANSION IS THE STARTING POINT

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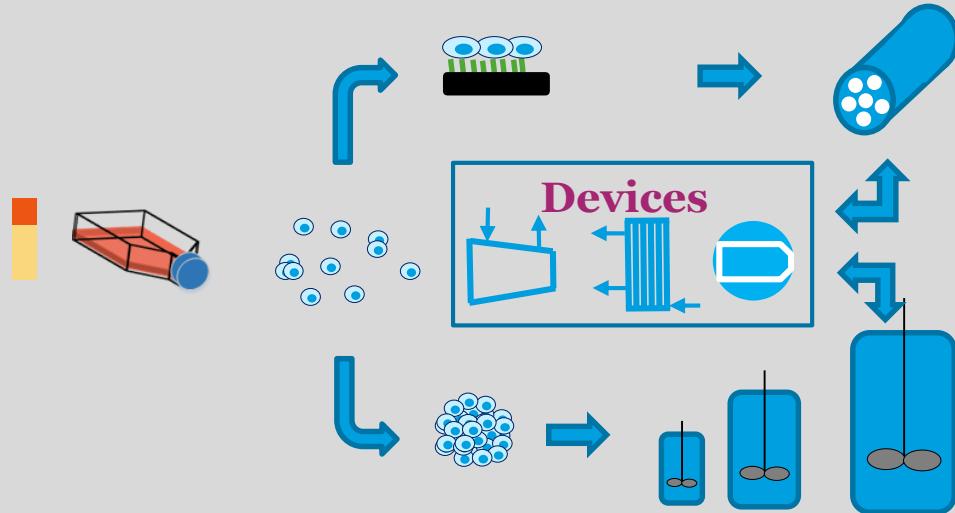
Key Challenges

- Product variations
- Process translation to GMP
- Process control
- Cost-prohibition

Priority Areas

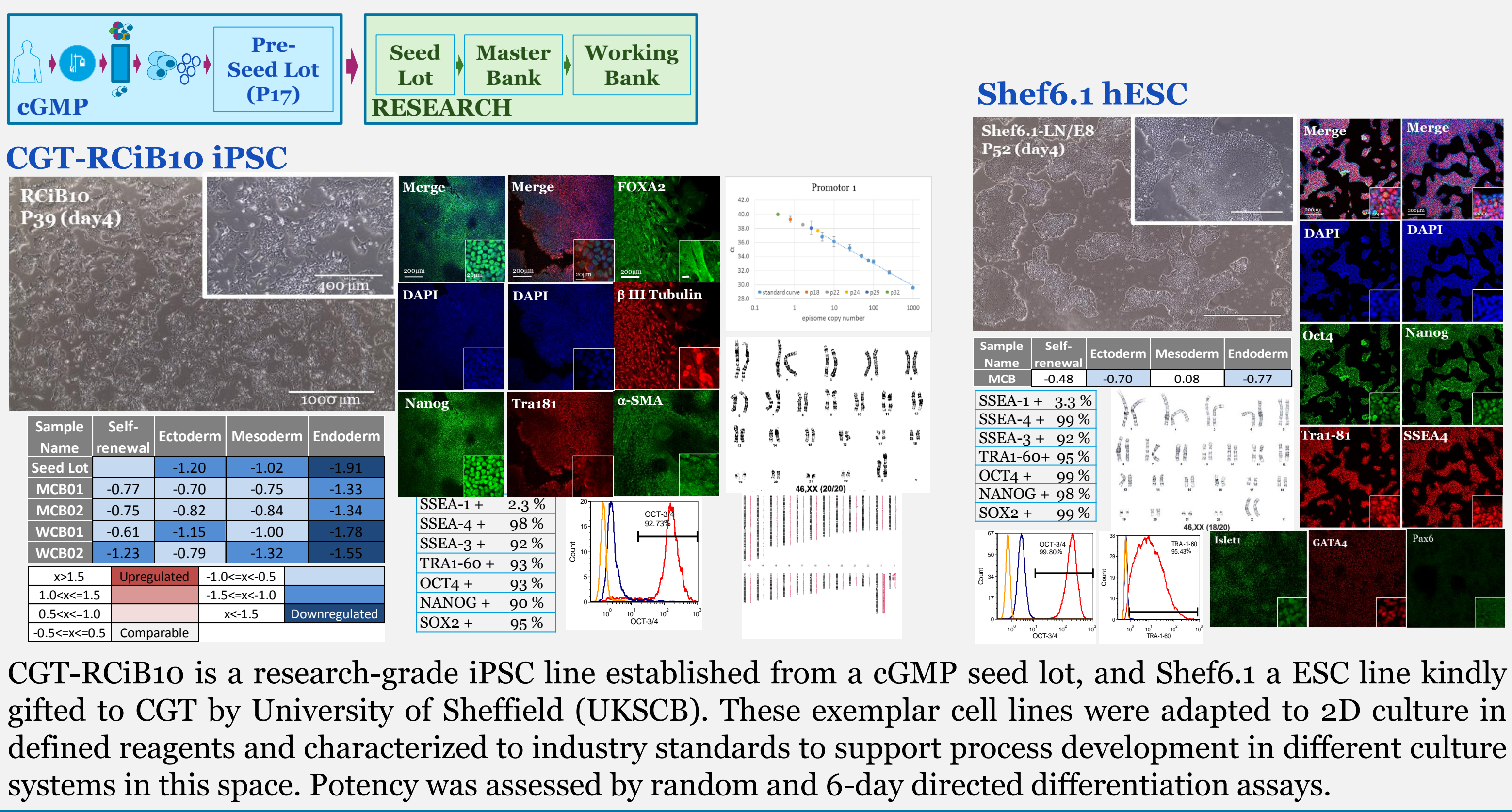
- Materials
- Automation/Scale-up/-out
- Process monitor/control
- Risk/cost/quality

Strategy

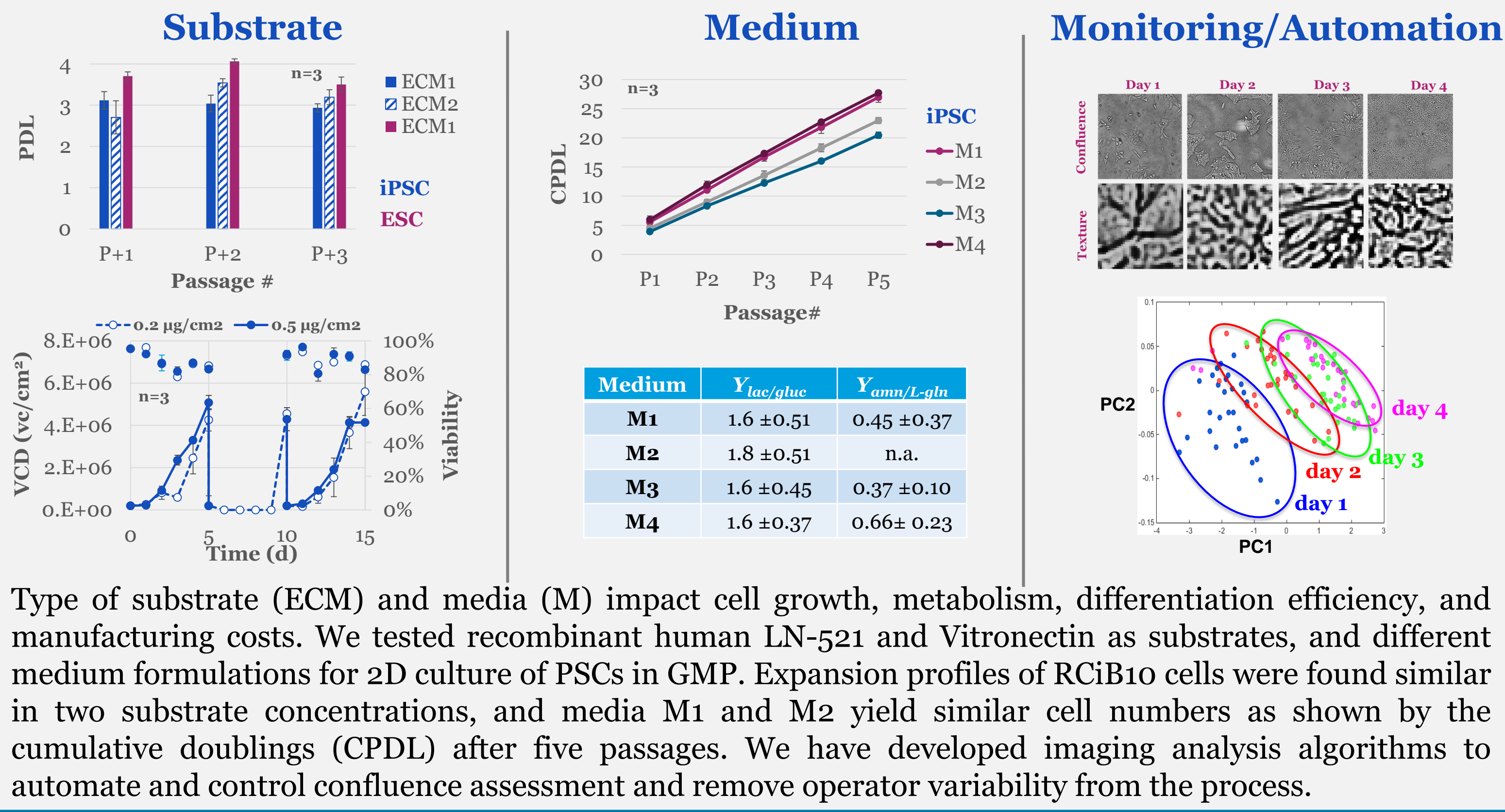


- Design space 2D/3D culture
- Automation (closed/continuous)
- Emerging technologies (fast processing)
- Control and quality (analytic development)
- Next Gen. CoGs reduction

Materials and CQAs

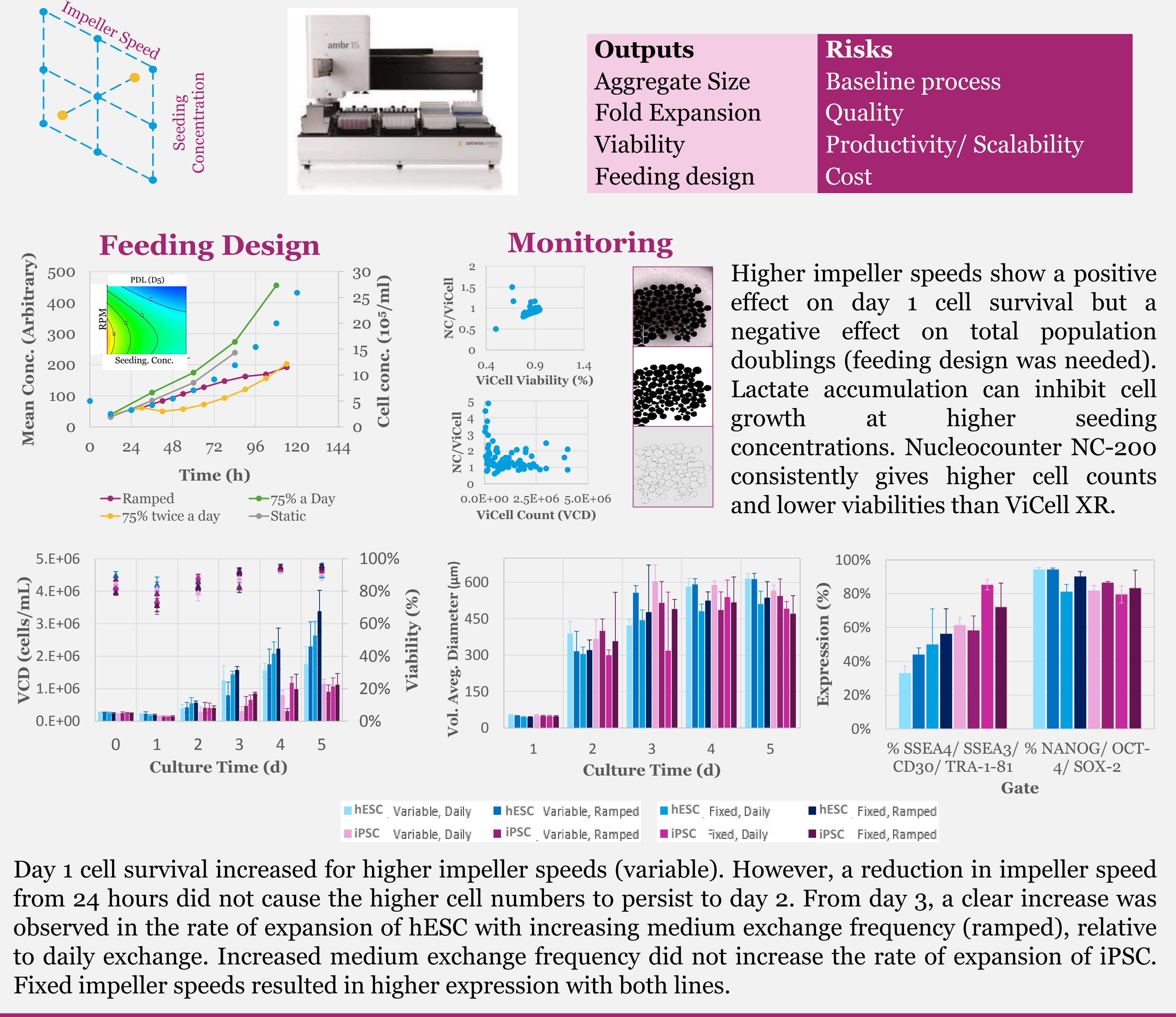


Seed Train

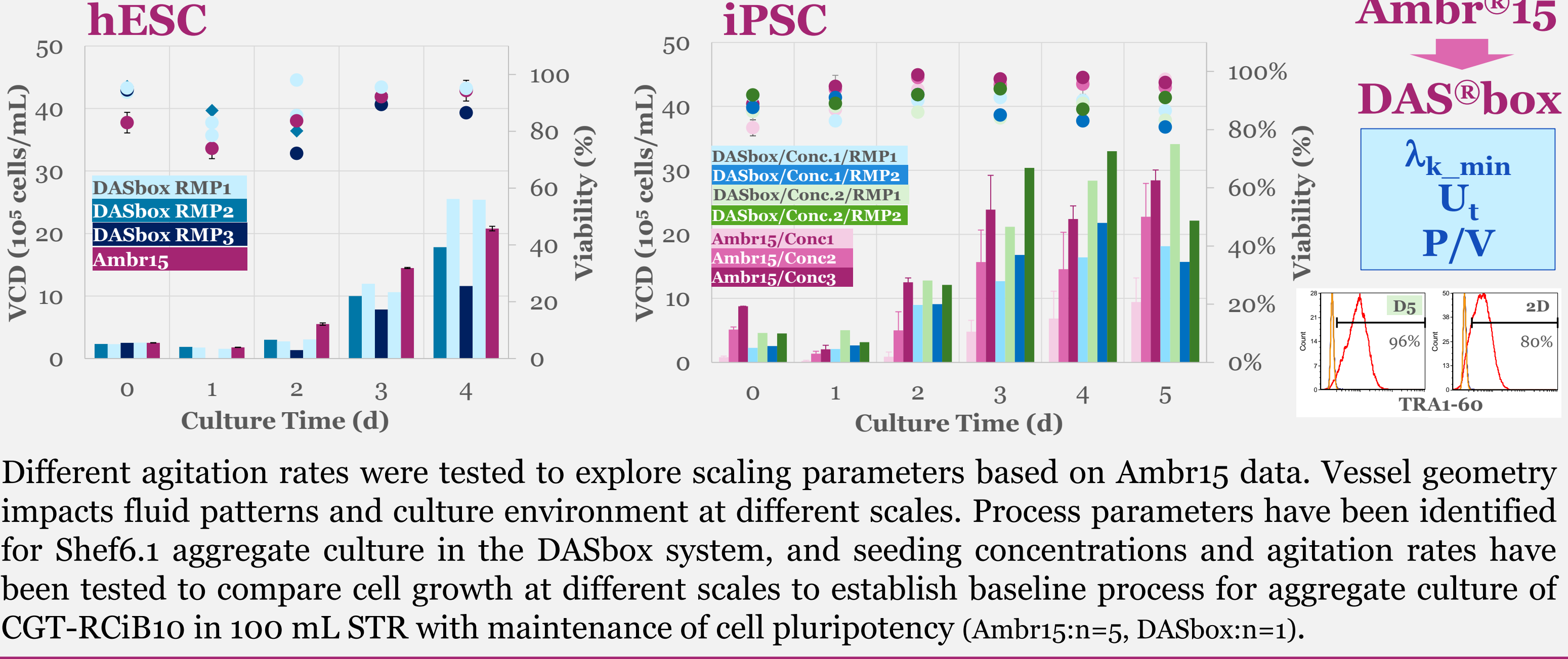


Aggregate Culture in STR

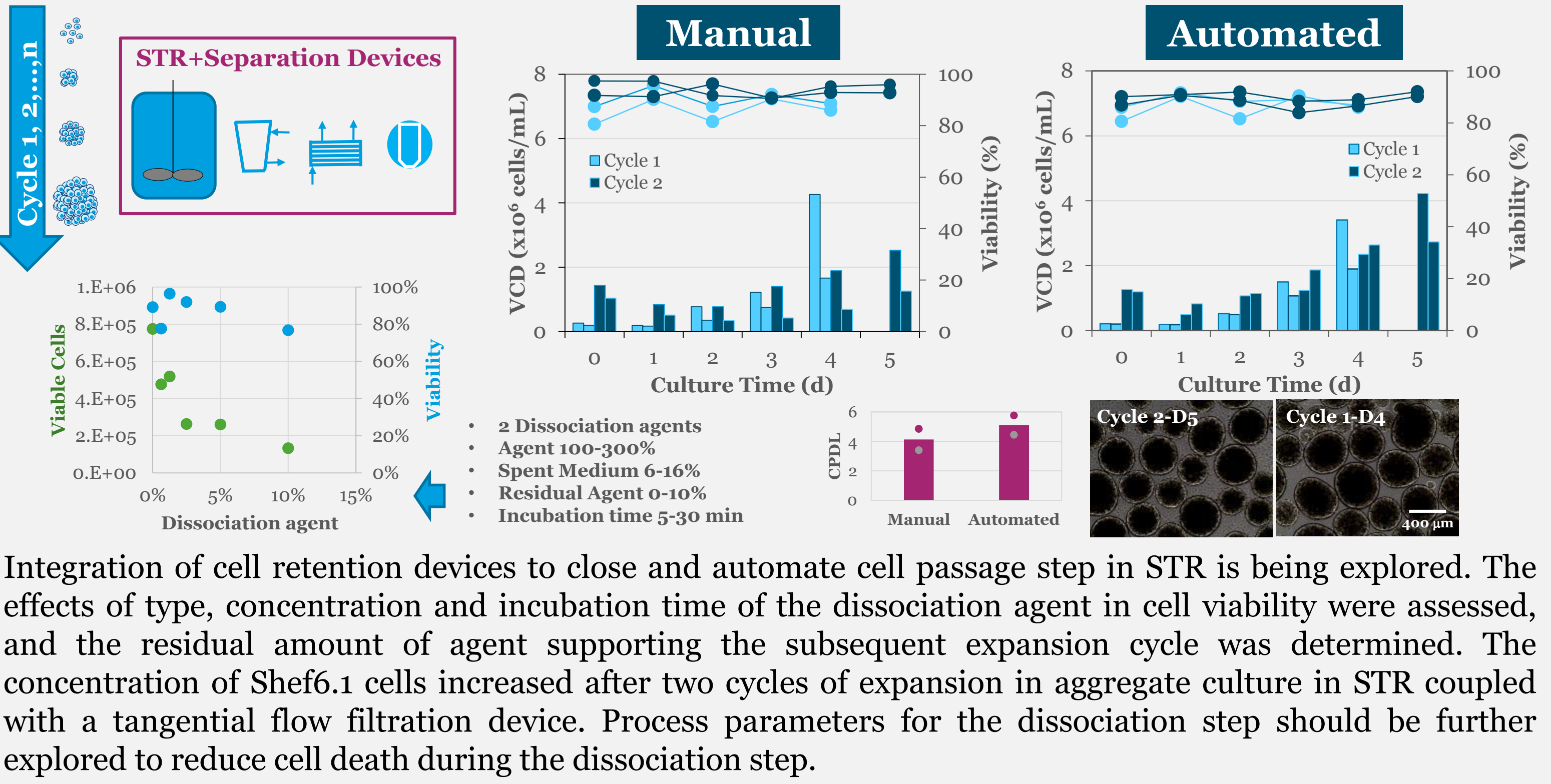
Operational Design



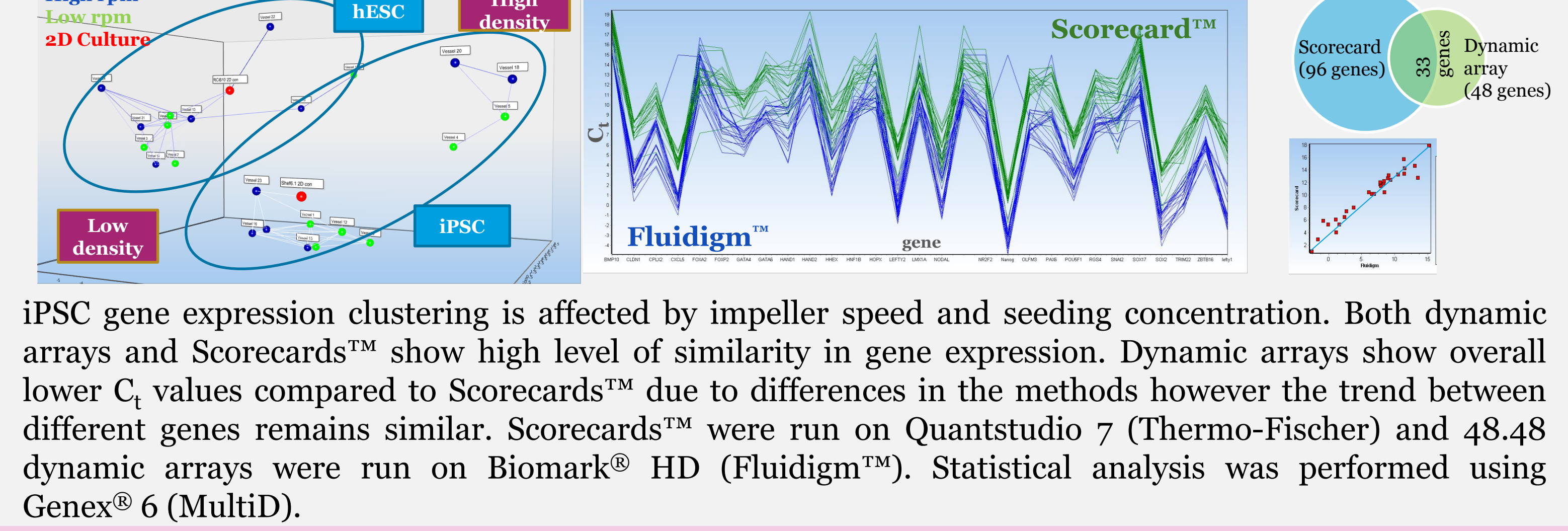
Baseline Process 0.1-L



Intensification



Analytical Development – dynamic array



Relevance and Ongoing work

- The results provide operational ranges of impeller speed, seeding concentration, and feeding regimes to assist establishment of baseline process and further scale-up of PSC expansion in STR.
- Data is promising for intensification of aggregate culture and potential continuous closed expansion and differentiation should be considered.
- Impact of automation in process cost/risk is being evaluated, as well as the potential for the use of medium key component mimetics.

We work with
Innovate UK

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