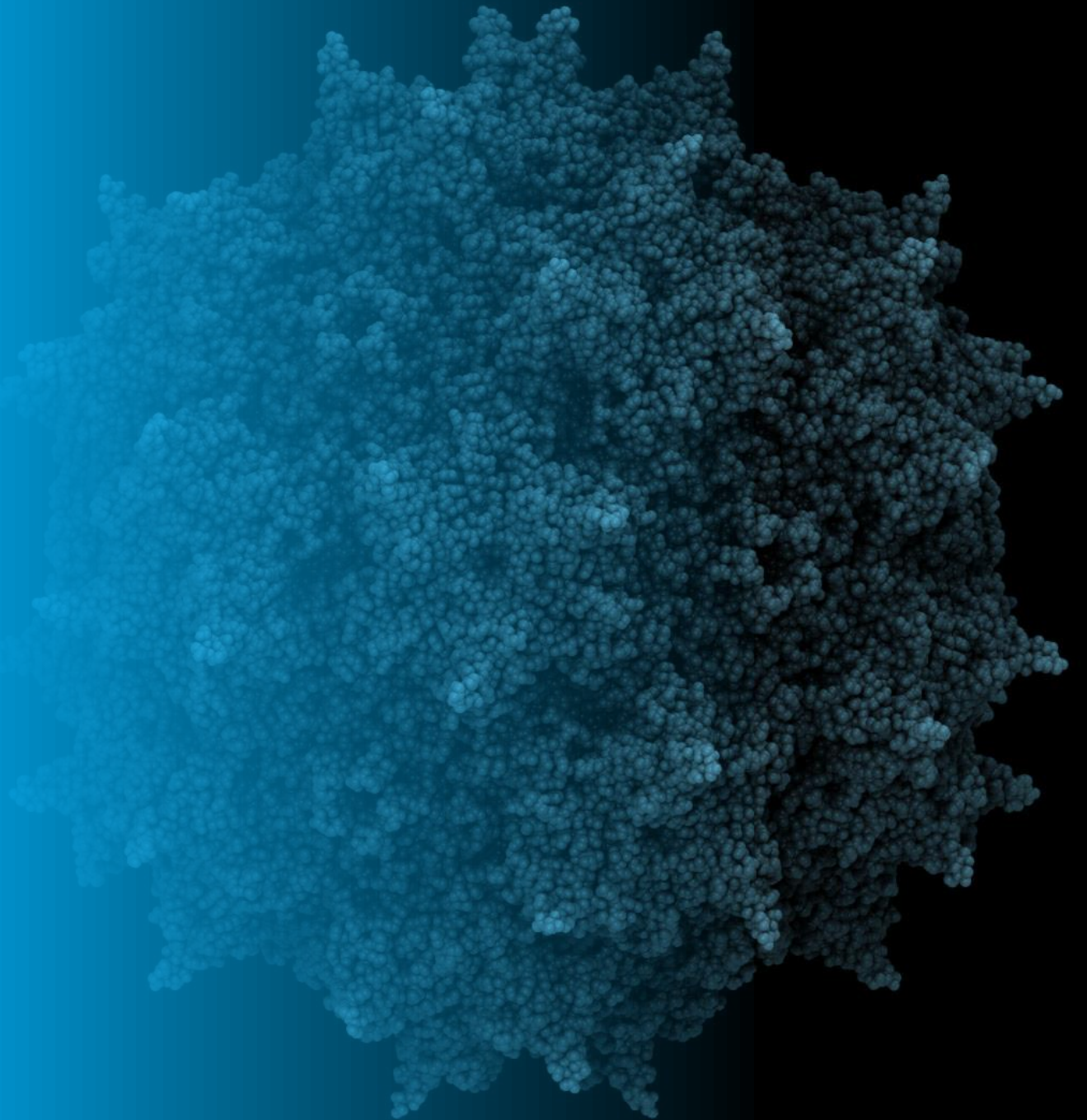


Towards the Industrialisation of Stem Cell-Derived Therapies

Dr Jahid Hasan



The Industrialisation Team

70

Team of dedicated scientists
Made up of process engineers, cell biologist, analytical scientists, immunologists, data scientists



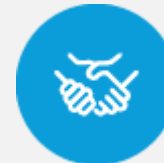
25

Average number of new project commencing each year
Typical project duration of 1 – 3 years

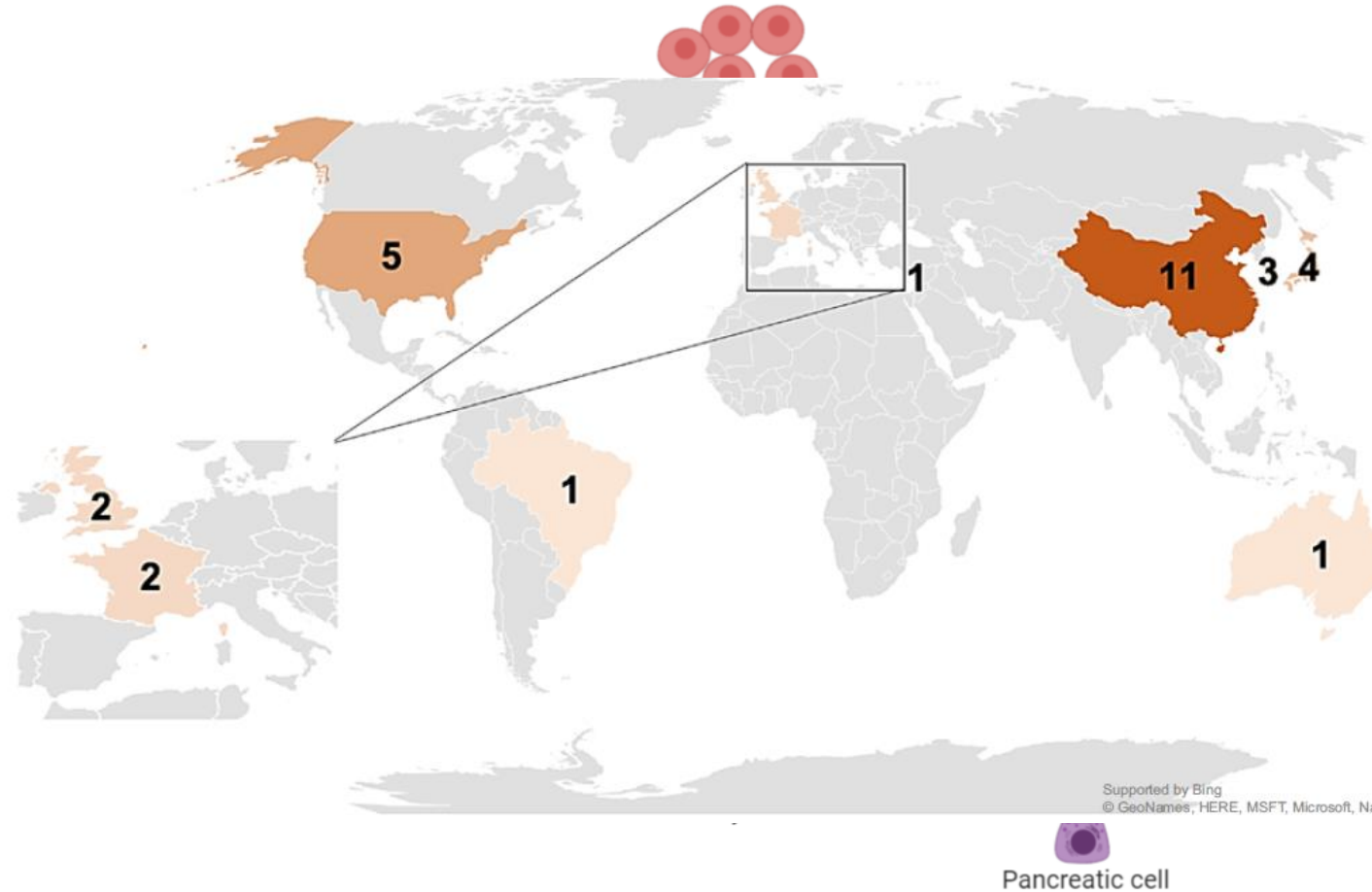


Collaboration

The team has worked on projects with large pharma,
SME's, leading academic groups and technology developers



22 ESC



8 iPSC

The scale of the challenge

Indication	Therapeutic cell type	Annual incidence in UK	Predicted cell/dose	Annual cell requirement
Type I diabetes	Pancreatic b-cells	15,000	$2 \times 10^6/\text{kg}$	2.4×10^{12}
Macular degeneration	Retinal epithelial	20,000	$0.5\text{-}2 \times 10^5$	2×10^9
Osteoarthritis	MSC/Chondrocytes	20,000	$2 \times 10^6/\text{kg}$	3.2×10^{12}
Liver Failure	Hepatocytes	12,000	1×10^8	1.2×10^{12}

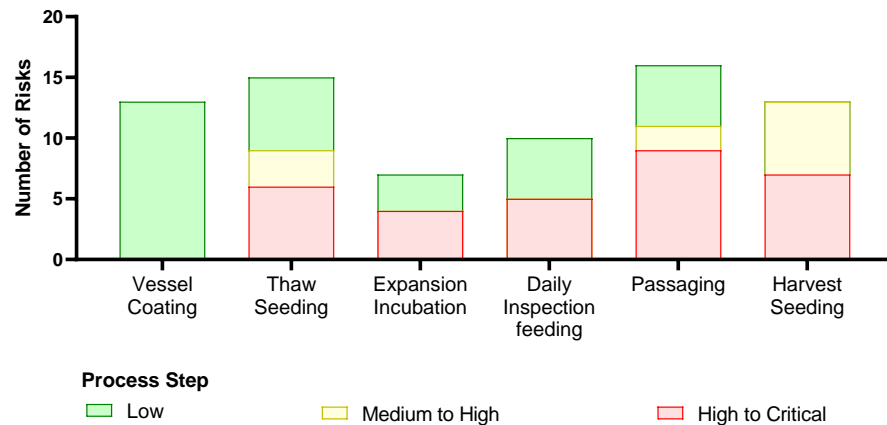
Current production paradigm



Thaw

PSC expansion

Differentiation



10¹² cells per year
 @ 2 x 10⁵ cells/cm² = 1200 CF10

Starting material



Complexity



Scale



Control



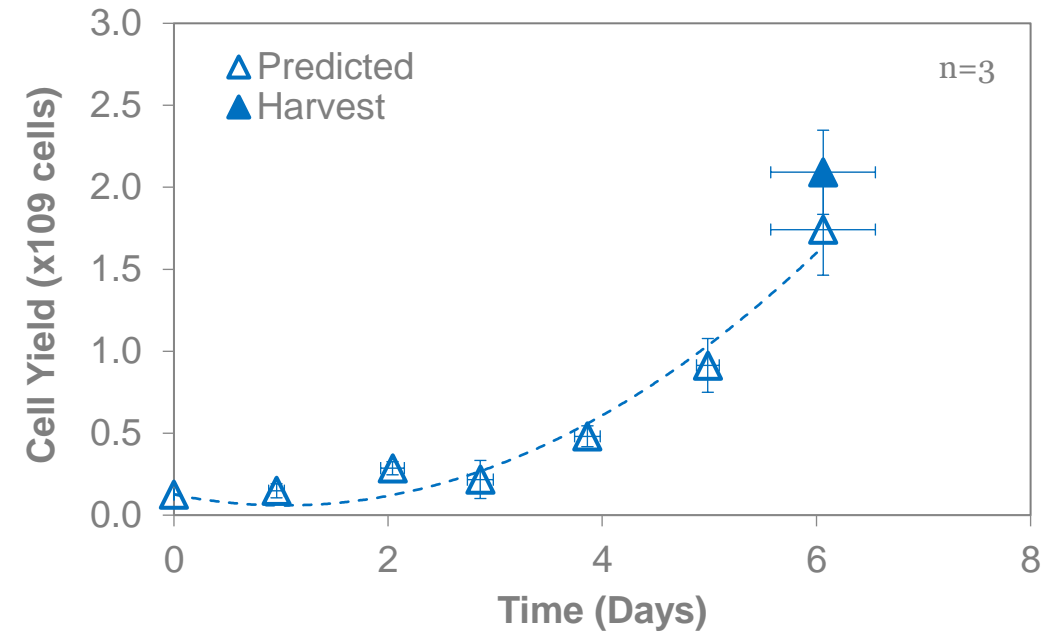
Adherent PSC expansion



TERUMOBCT

Automated vs. Manual	
Labour	↓ 67%
CoGs	↓ 40%
Capex	↑ 9%
Throughput	↑ 250%

Surface area = 2.1 m² = ~4x CF10

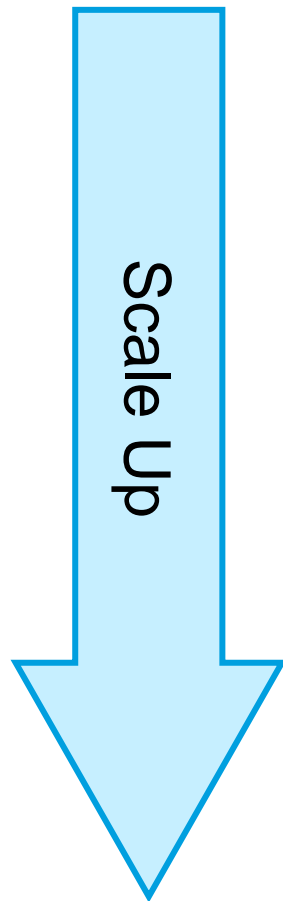
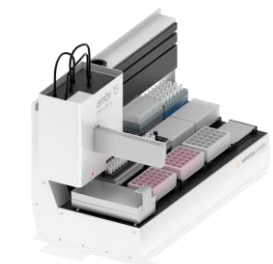


10¹² cells per year
@ 2 x 10⁵ cells/cm² = 300 Quantum's

Assure product manufacture



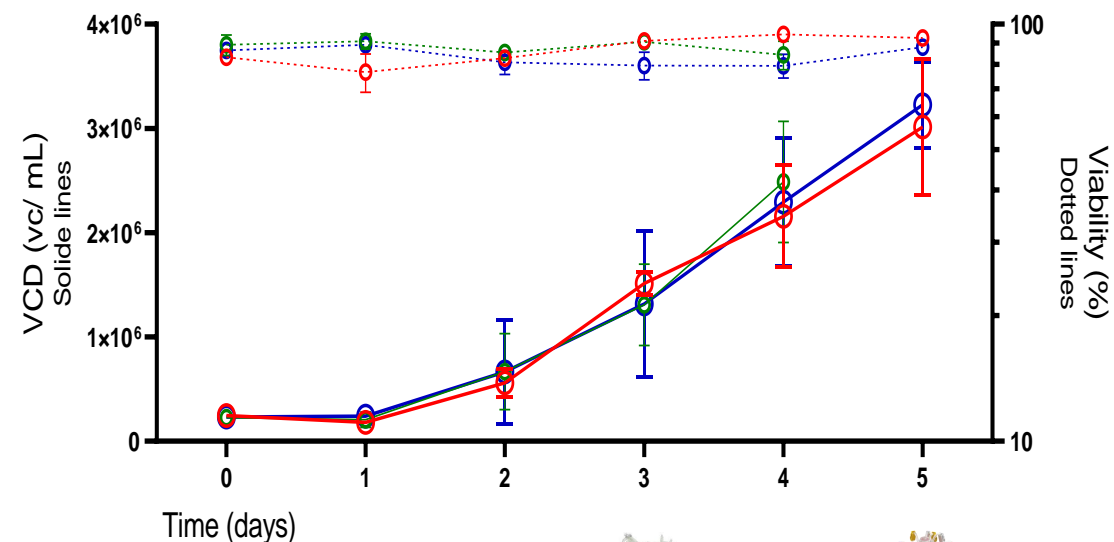
Suspension PSC expansion: Scale Up



Screen

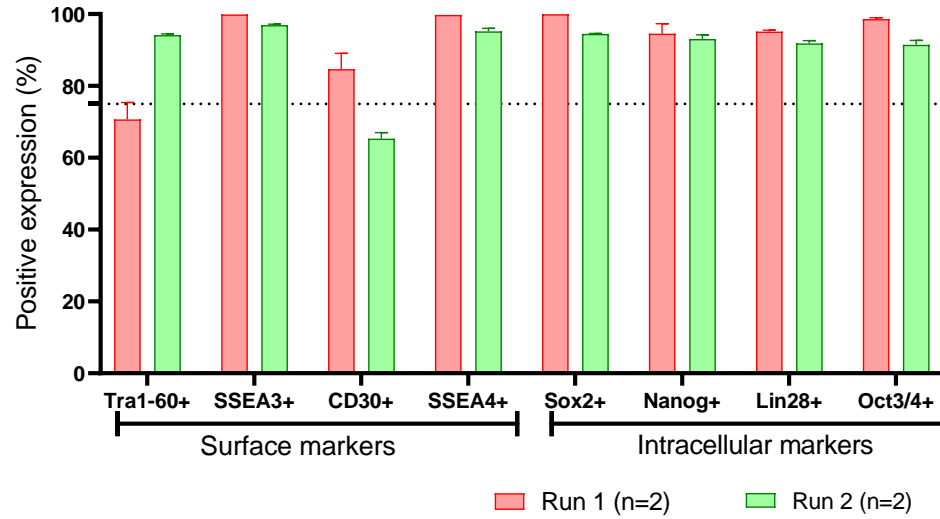
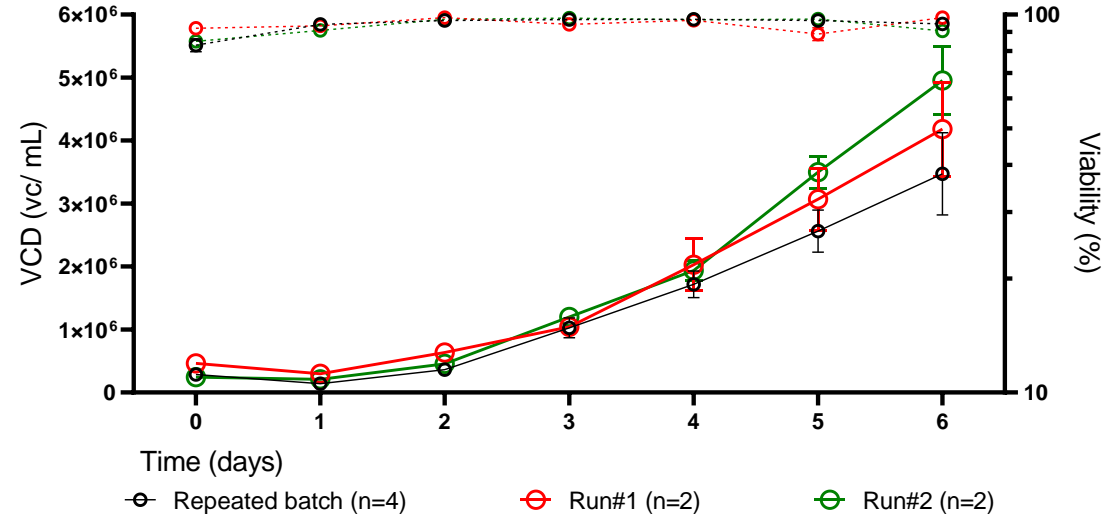
Optimise

Proving

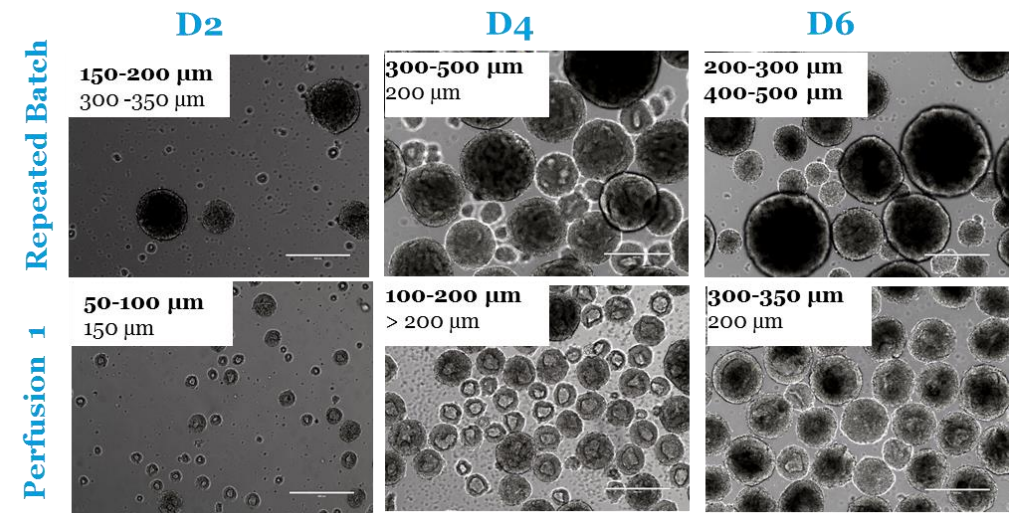
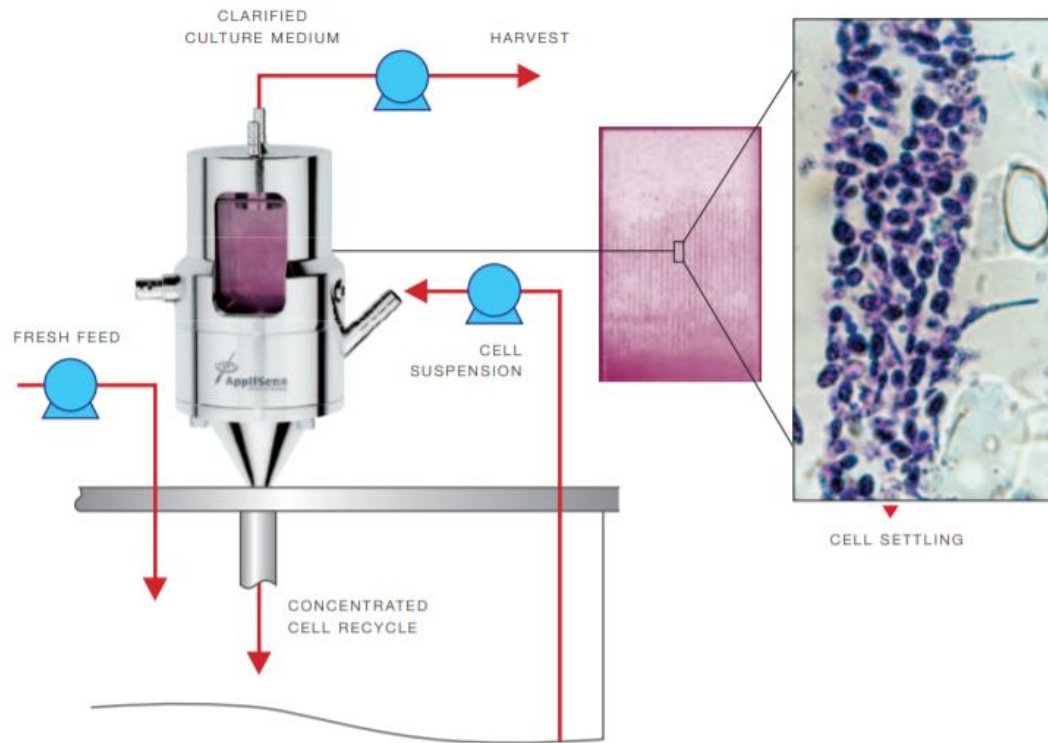


10¹² cells per year
@ 2 x 10⁵ cells/cm² = 300 Quantum's

Closing the process from start to finish



Perfusion: increased yield and quality



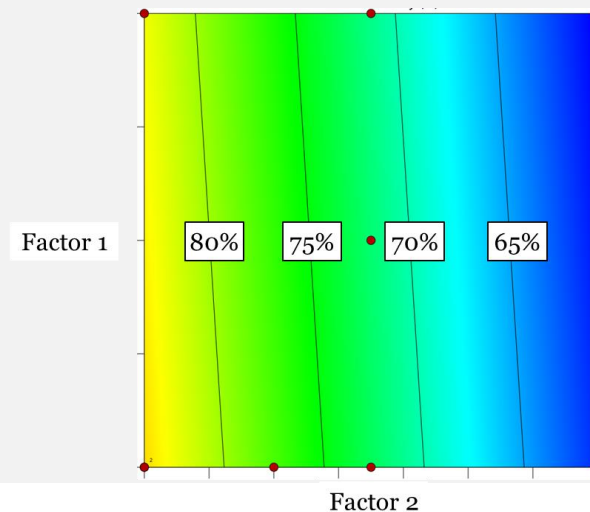
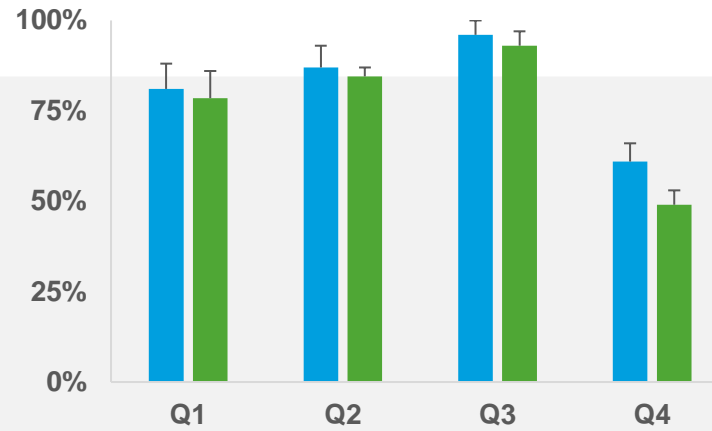
Automated buffer exchange

Method

- Fluidised bed centrifugation (kSep[®])
- Spinning membrane filtration (LoVo[®])

Cell separation technologies

- For removal of passaging agent
- For change to differentiation medium
- For before and after selection, transduction, etc.



kSep[®]



LoVo[®]



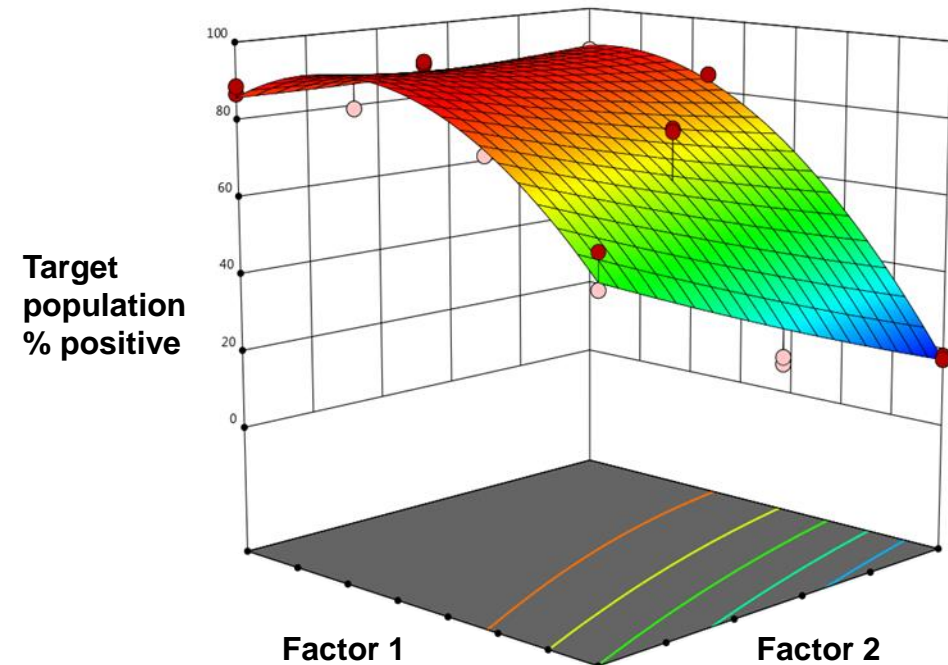
DoE as a differentiation optimisation tool

Methodology developed to optimise differentiation processes to in-house iPSC bank

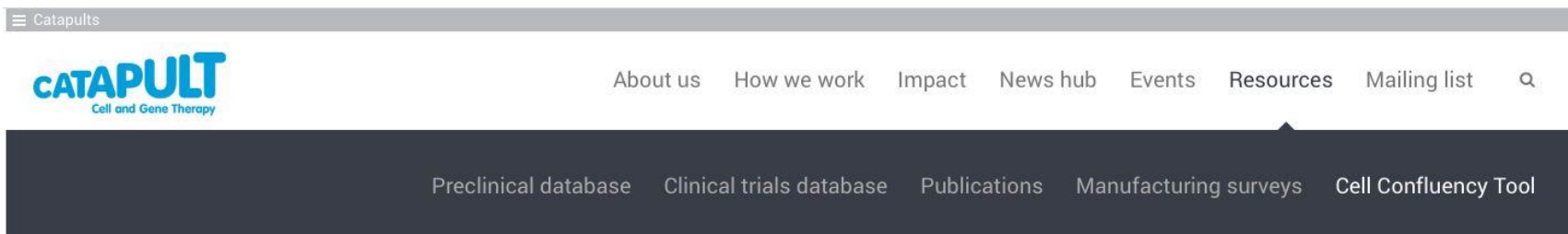
Identification of universally scalable metric

Potential to use as GMP cell line screening tool

Increased process understanding can be applied to achieve CoGs reduction



2D Confluency assay – Online WebApp



Cell Confluency Tool

Accurately determine the confluency of cells using this online tool. Estimation by observing and comparing the space occupied by the cells visually is one method but our research shows that even the most experience scientists can get the estimations wrong.

How it works



Snap a picture under the microscope



Upload to the cell confluency tool

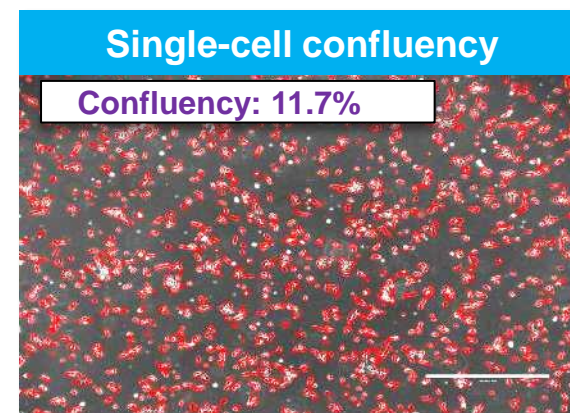
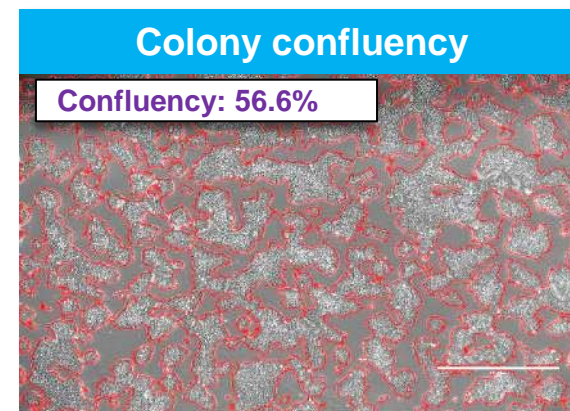


Get accurate coverage percentages



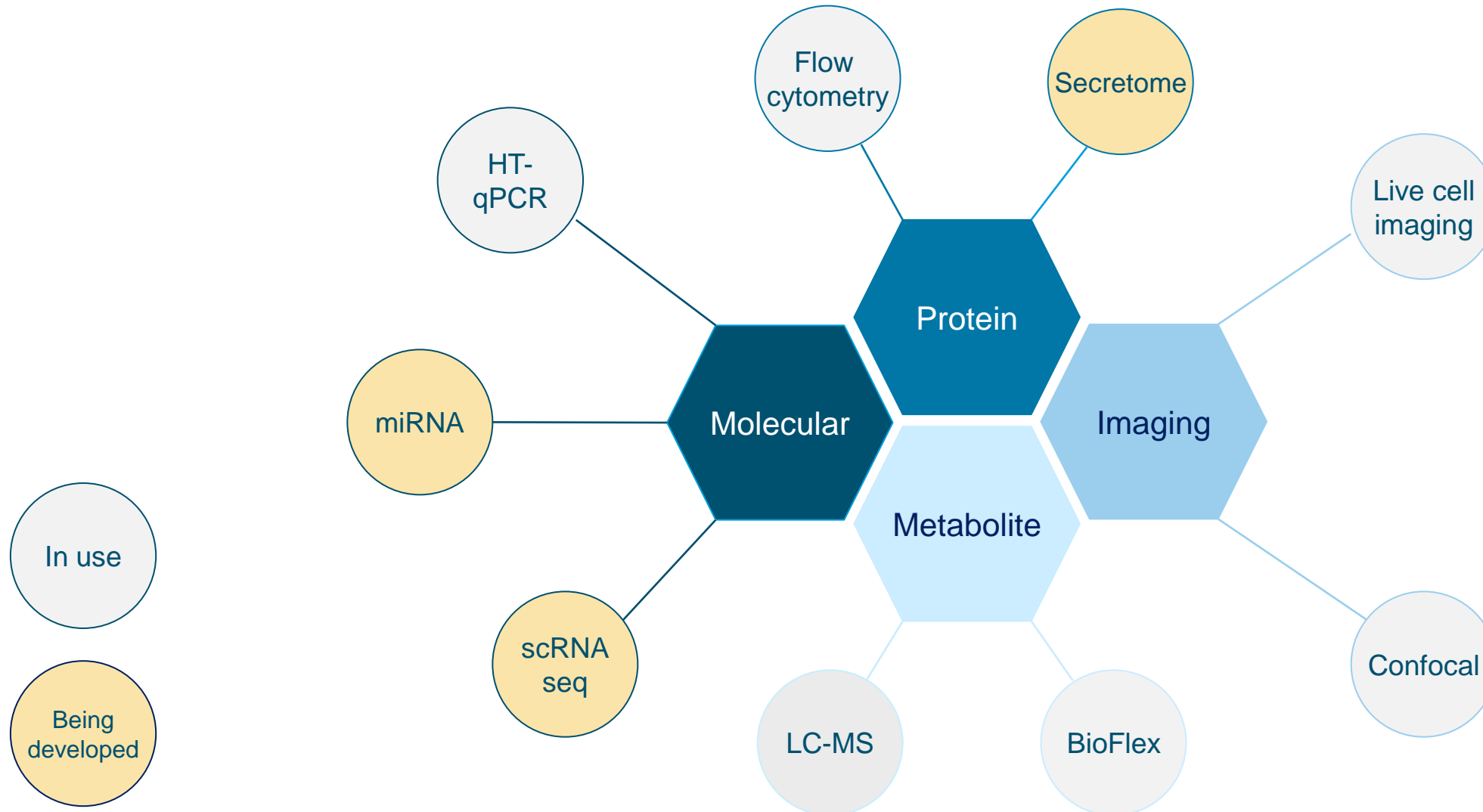
Download results as an excel file

Contact us



<https://ct.catapult.org.uk/resources/cellconfluencytool>

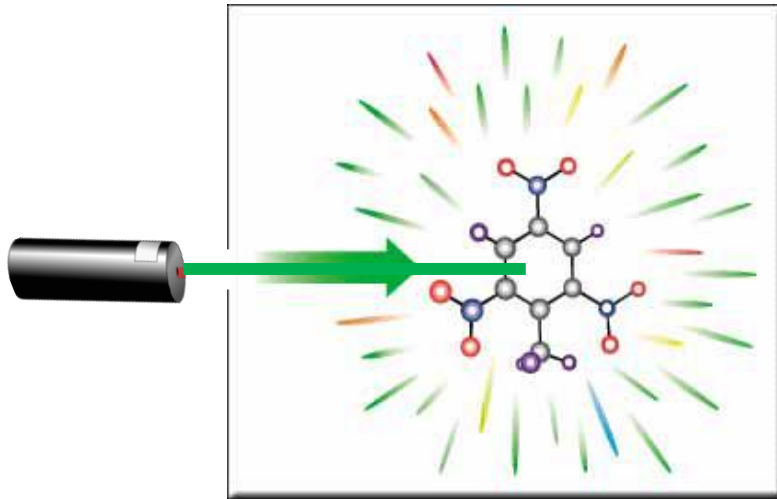
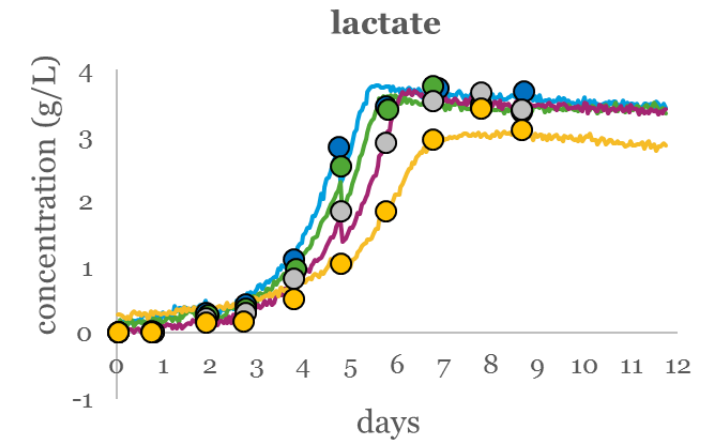
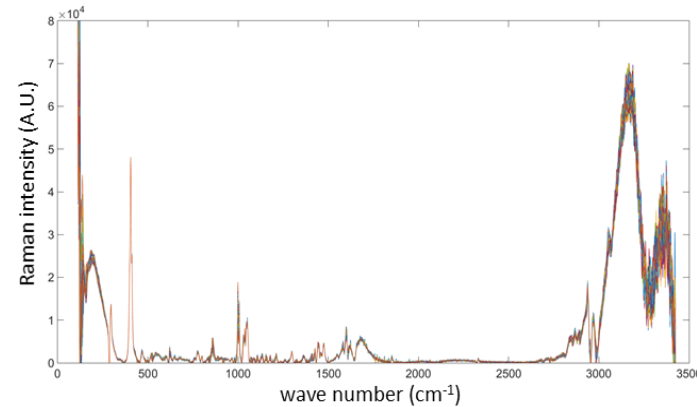
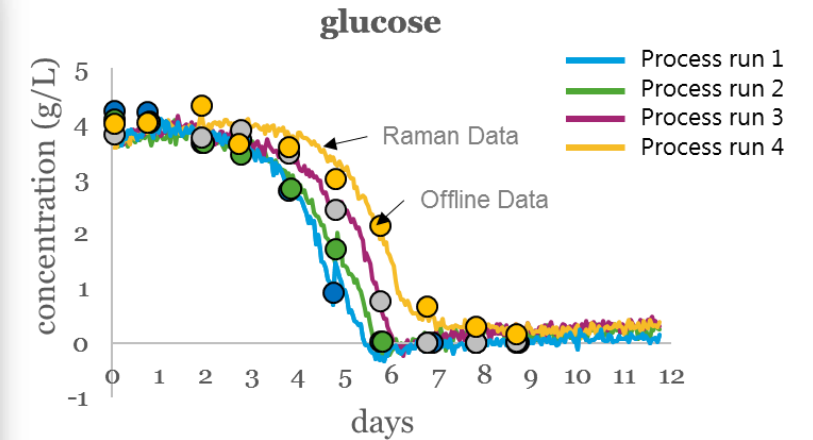
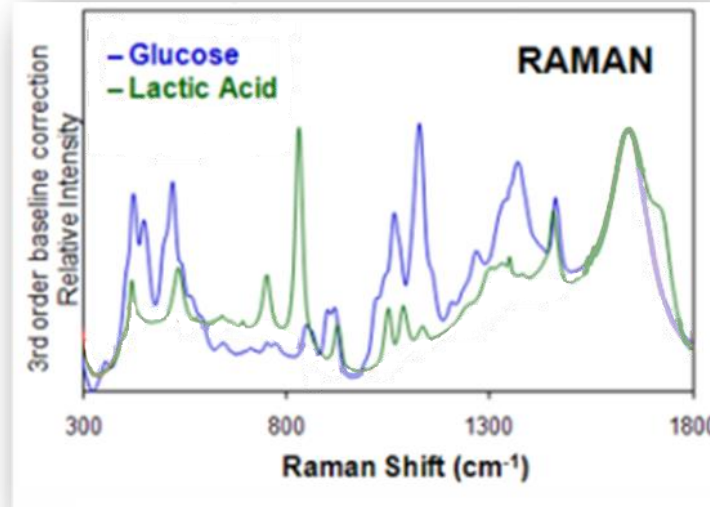




PAT: Raman as example

Raman Spectroscopy

Used to observe molecular vibrations
Identify and quantify measuring changes in the wavelength of laser light



Stem Cell Expansion and Differentiation Team



Mustafa



Matthew



Moira



Marcia



Juline



Iris



Natacha



Elena



Jahid



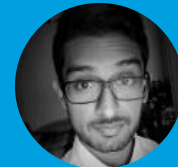
Rhys



Carolina



Esther



Mudith



Juan



Juan-Mi



Kamilia



Mallika



John



Rob



Sam



Oliver



Chris



Marianne



Isobelle

CATAPULT

Cell and Gene Therapy

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