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Multimodal data handling: opportunities, challenges and solutions

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Growing interest in multivariate data and analytics

	Adaptive control	Process development	Rapid release
Opportunities	• Scale up/out • Corrective actions • Optimal actions	• Optimisation • Reduce cost-of-goods • Reduce cycle time	• Patient needs • Reduce QC burden • Real time release
Challenges	Technology Algorithms Knowledge Validation	Data capture Data processing Data interpretation	Systems Validation Adoption Review by exception
Solutions	Analytical strategies Integration Automation	Process analytical technologies Multivariate data analysis	Automation Artificial intelligence

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Industry drivers

International Conference on Harmonisation (ICH) guidelines

- Bring together regulatory authorities and *pharmaceutical* industry to ensure that safe, effective, and high quality medicines are developed in the most resource-efficient manner.

Quality-by-Design

- "A systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science (ICH Q8(R2))"
- Design-of-Experiments (DoE)

Process Analytical Technologies

- Mechanism to design, analyse, and control *pharmaceutical* manufacturing processes through the measurement of Critical Process Parameters (CPP) which affect Critical Quality Attributes (CQA).
- Multivariate data acquisition and data analysis tools

Multimodal data integration – driving process innovation

Different data formats from different analytical platforms

multivariate data to drive innovation

Structured, actionable data

Process and material knowledge

Improved processes & products

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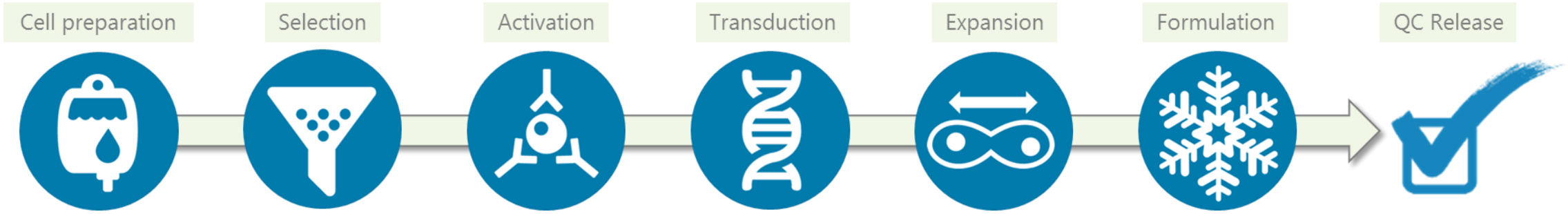
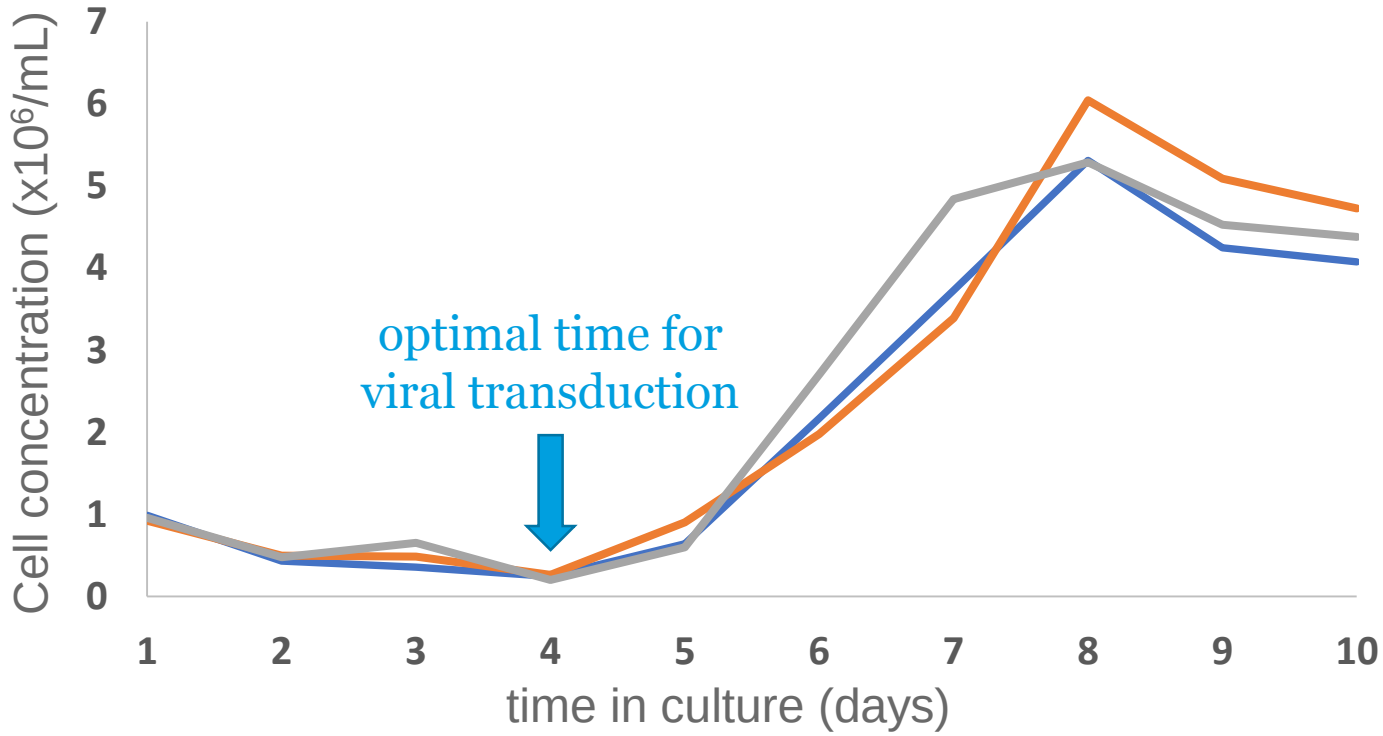
Example – monitoring immunotherapy manufacture in bioreactors





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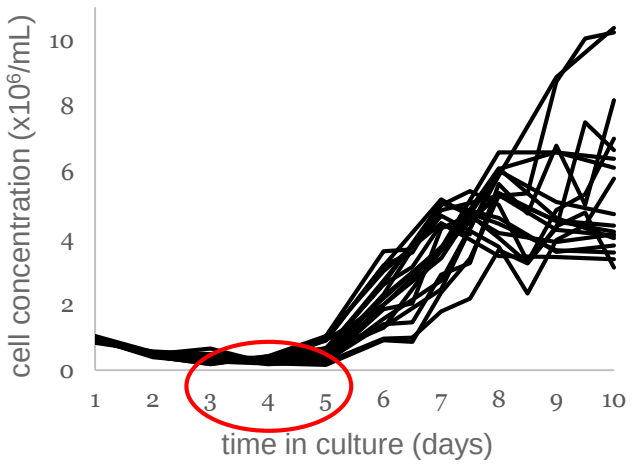
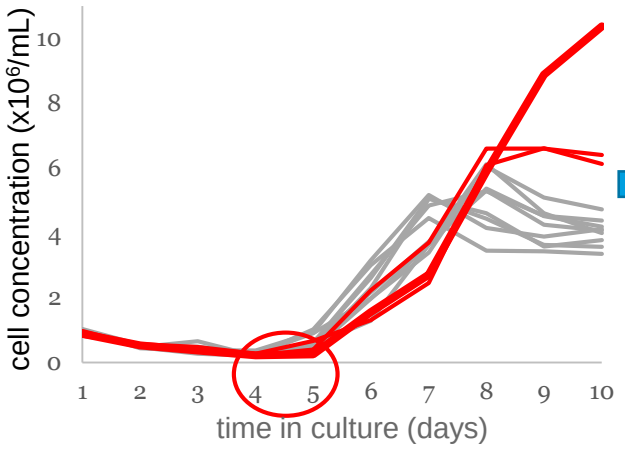
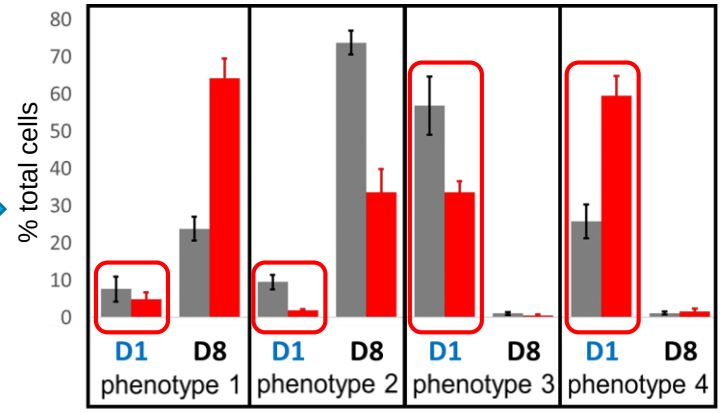
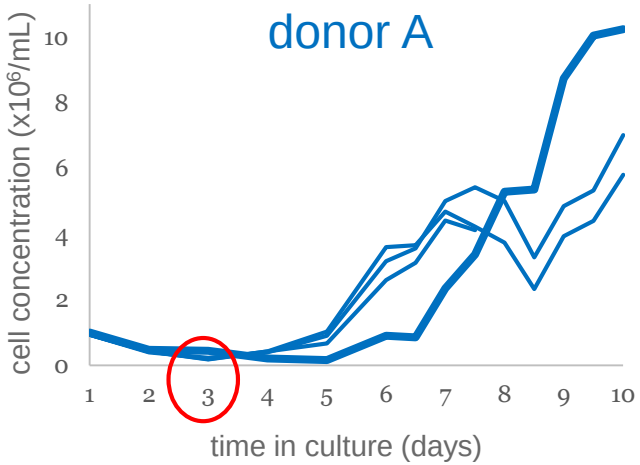
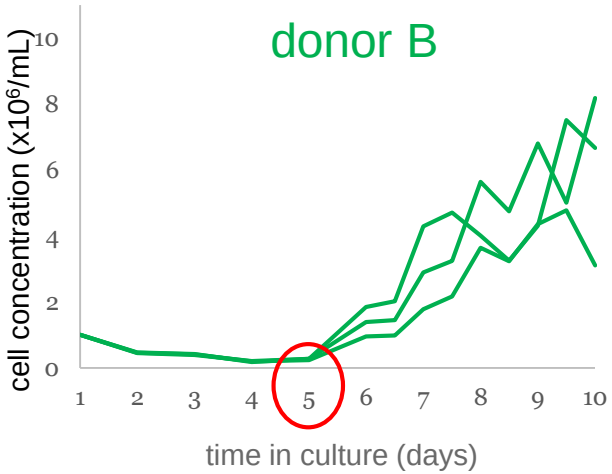
Process variability – T cell expansion with healthy donors











Causes of variability:

- Composition of starting material?
- Process?

Need for in process control

What is important to measure?

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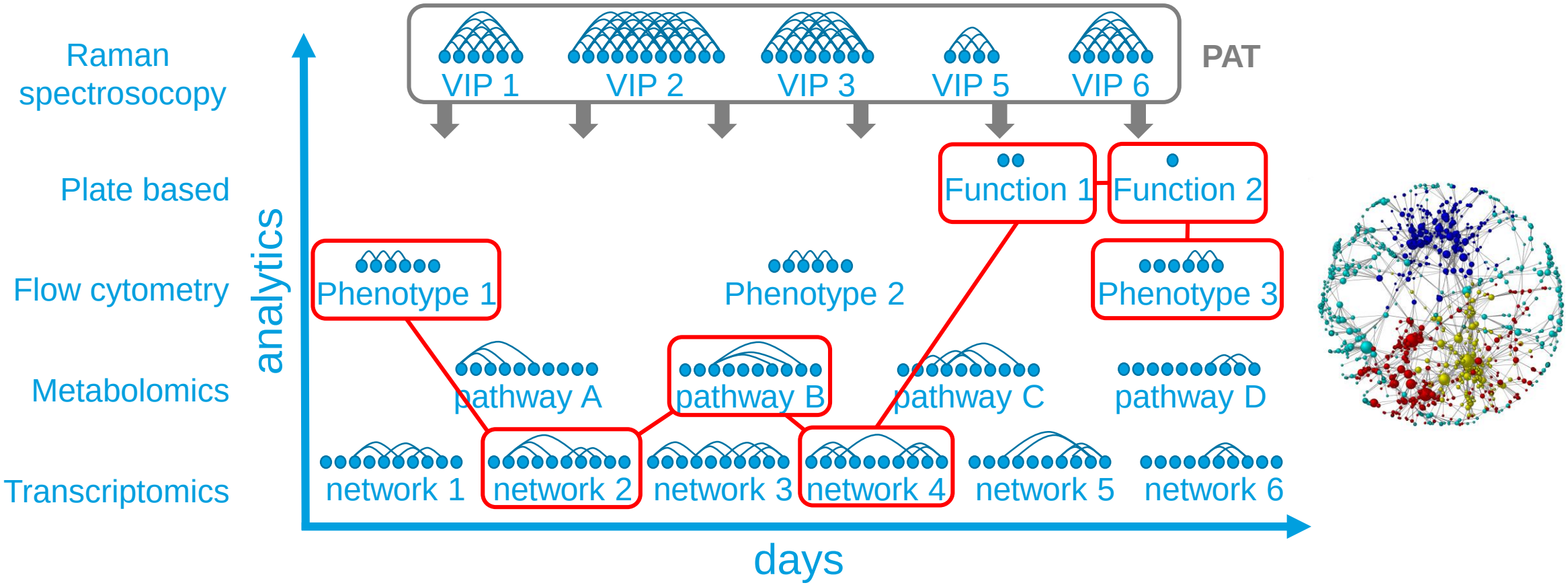
Analytics available for understanding the biology in relation to the process



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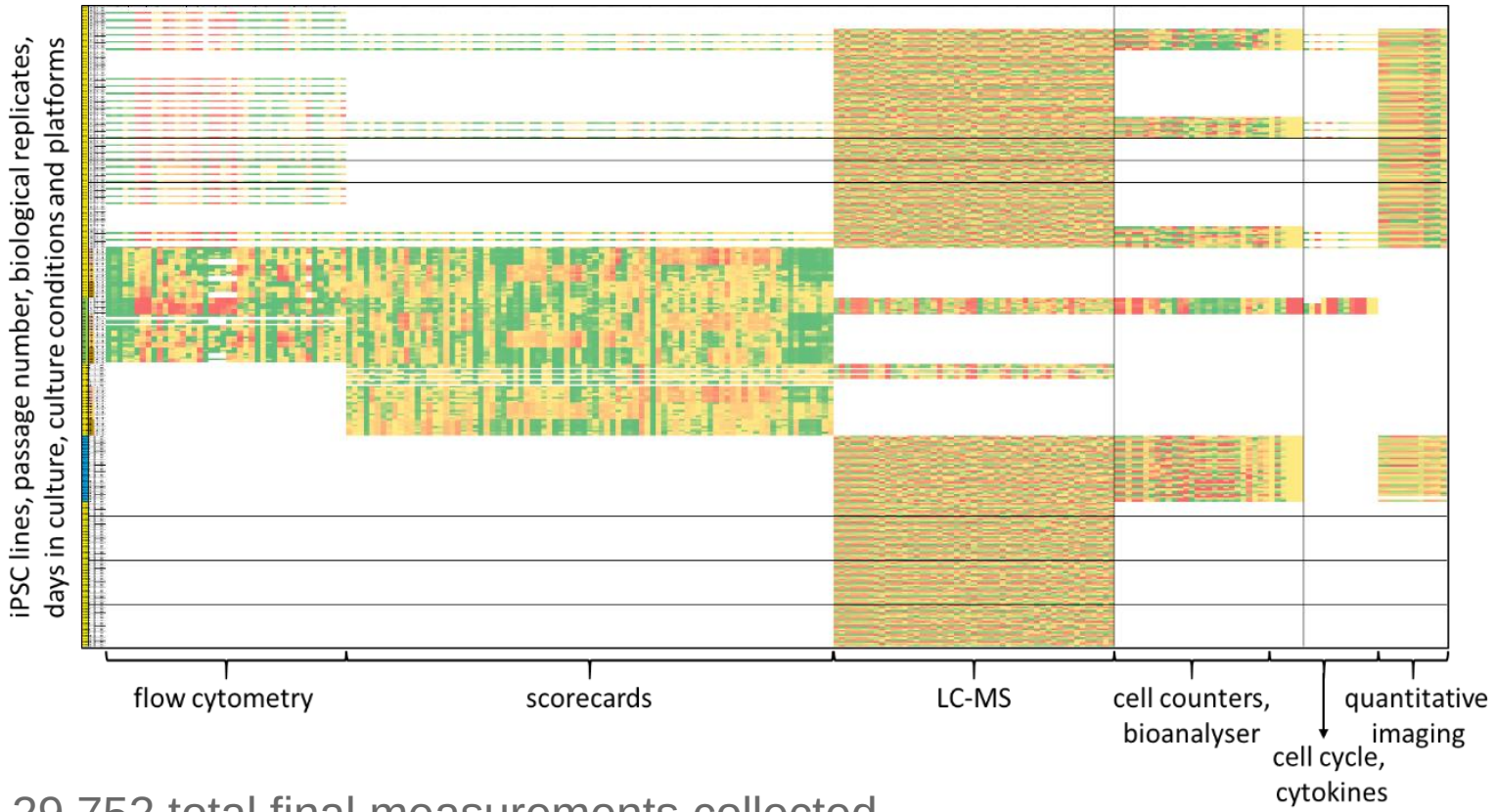
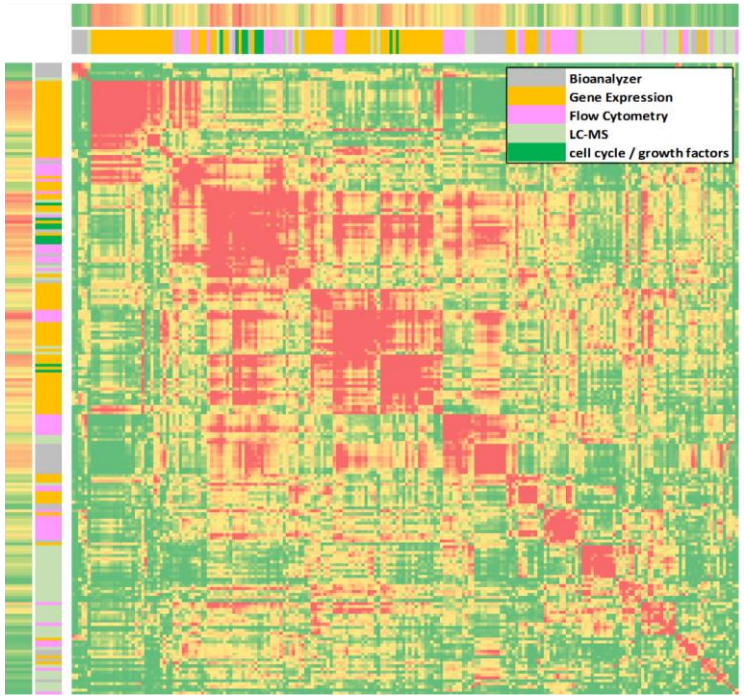
Data challenges for the implementation of PAT – at/off-line measurements





29,752 total final measurements collected
19,118 measurements retained for MVDA

- Fragmented datasets
- Missing data
- Multimodal (different types)

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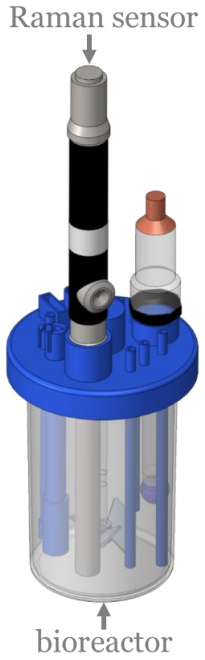

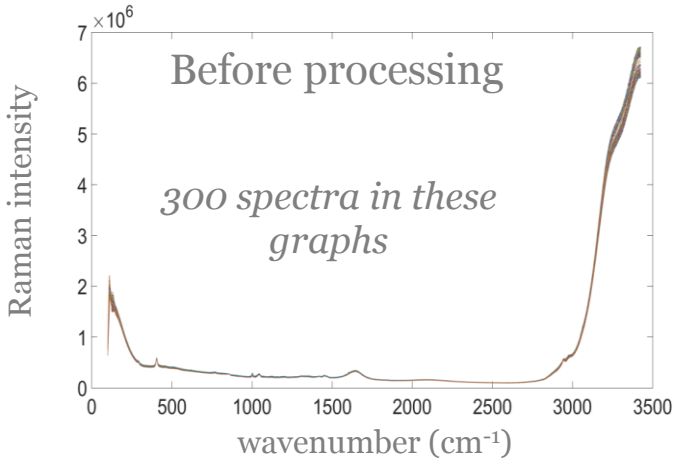

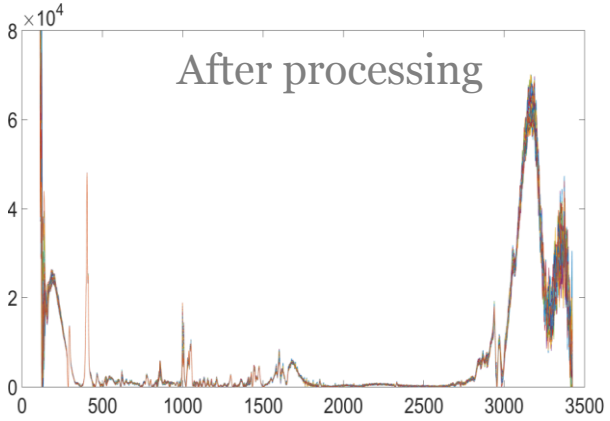

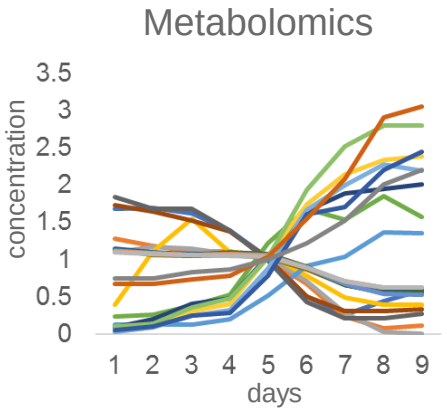

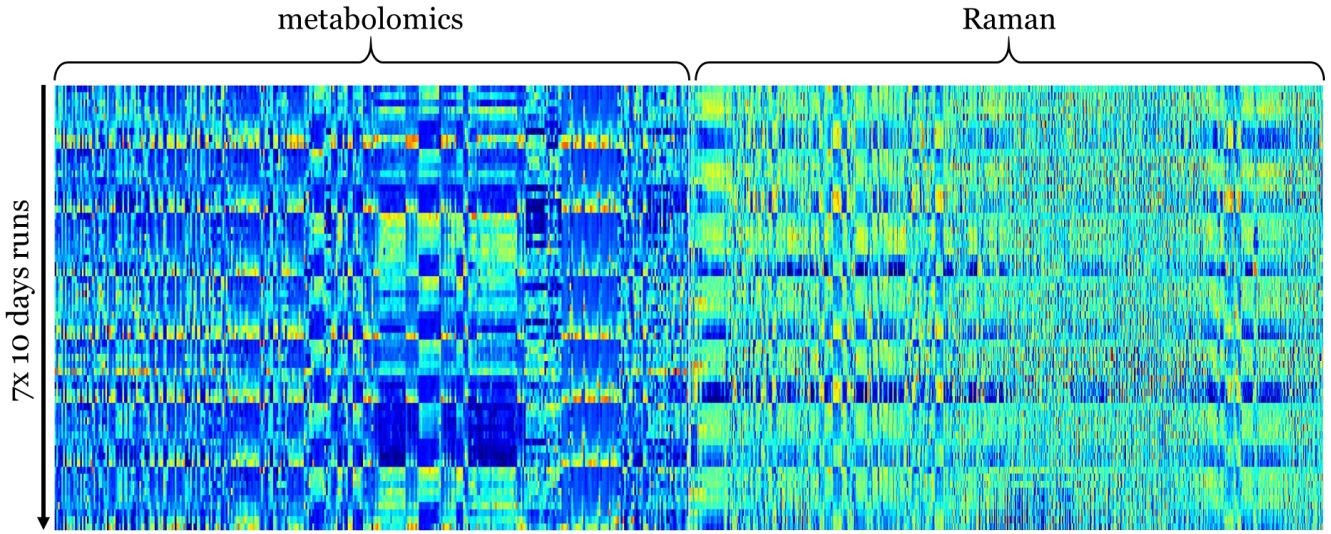

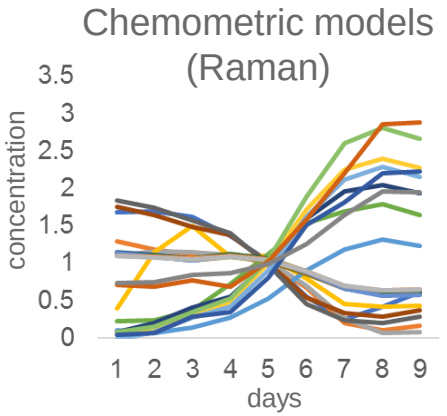

10-15 million data points

- Pre-processing
- Modelling
- Validation
- Real-time implementation

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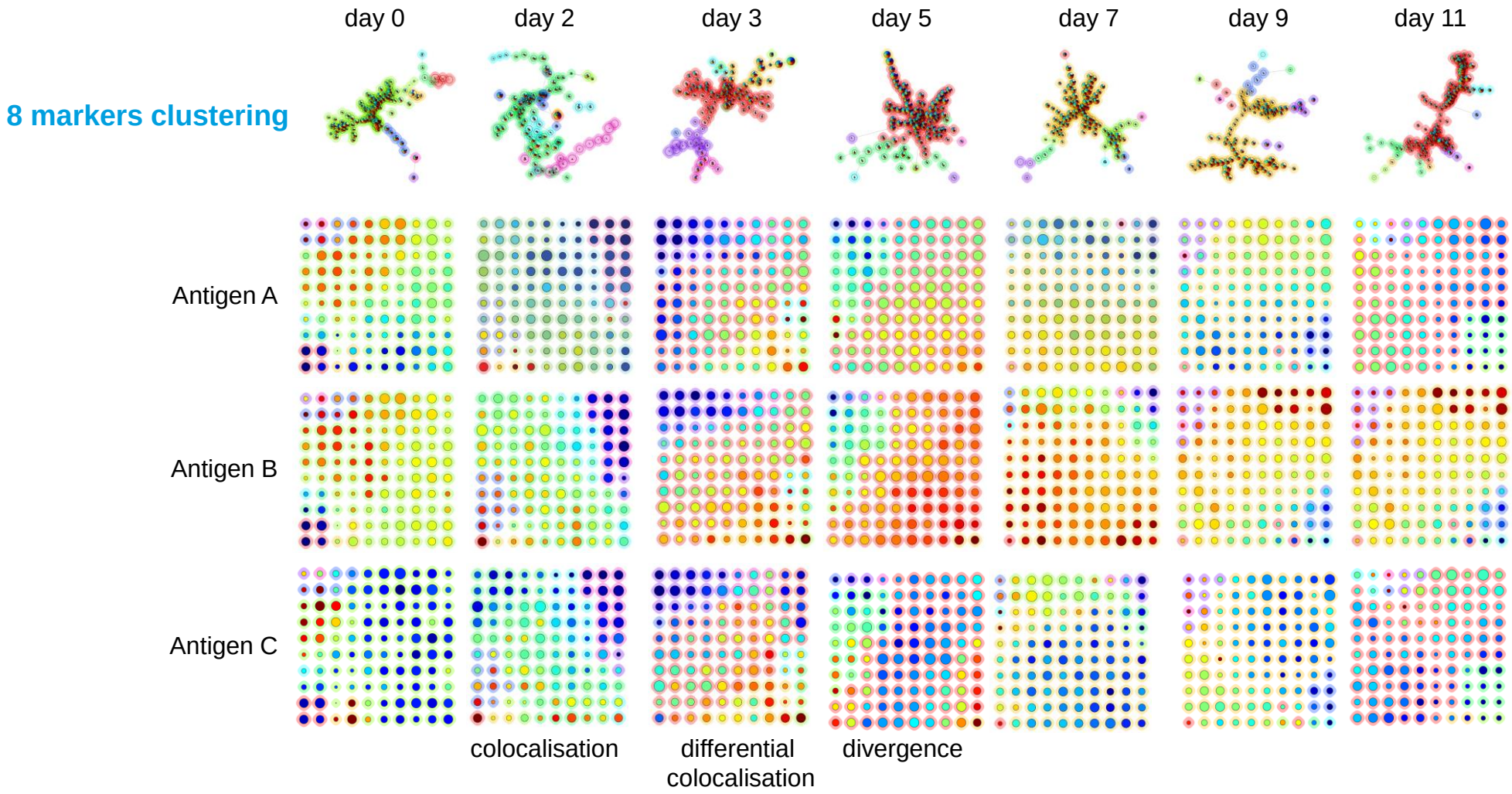
Opportunities for augmented information, unsupervised machine learning



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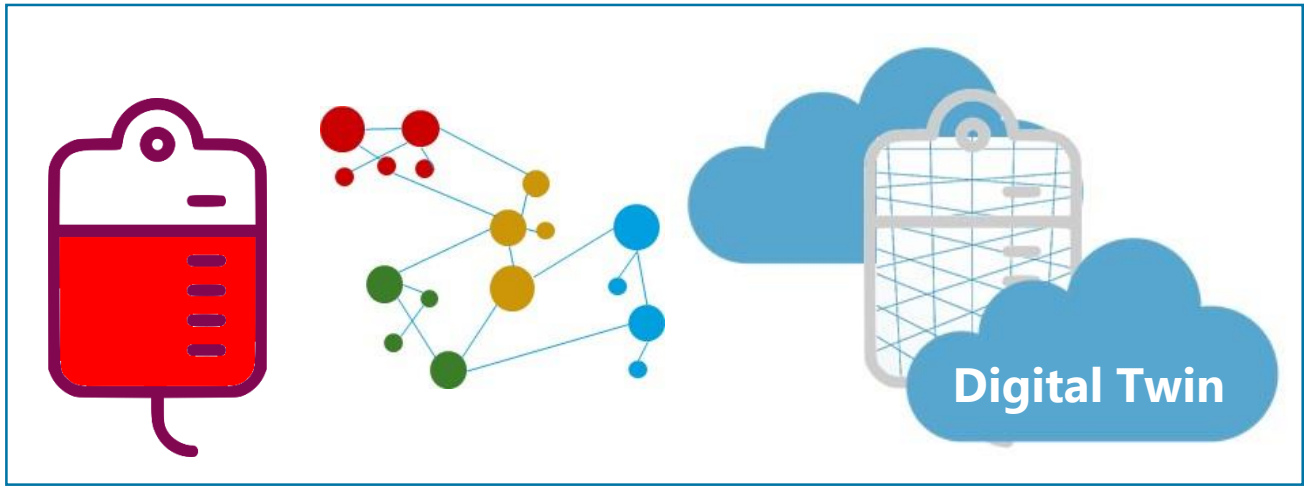
Future looking – *In-silico* digital twin to support process improvement

In-silico modelling, process simulation, artificial intelligence



Targeted and reduced experimentation

Robust, optimised processes

Improved process understanding

Soft sensors and augmented reality

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Thank you for your attention…

Questions welcomed