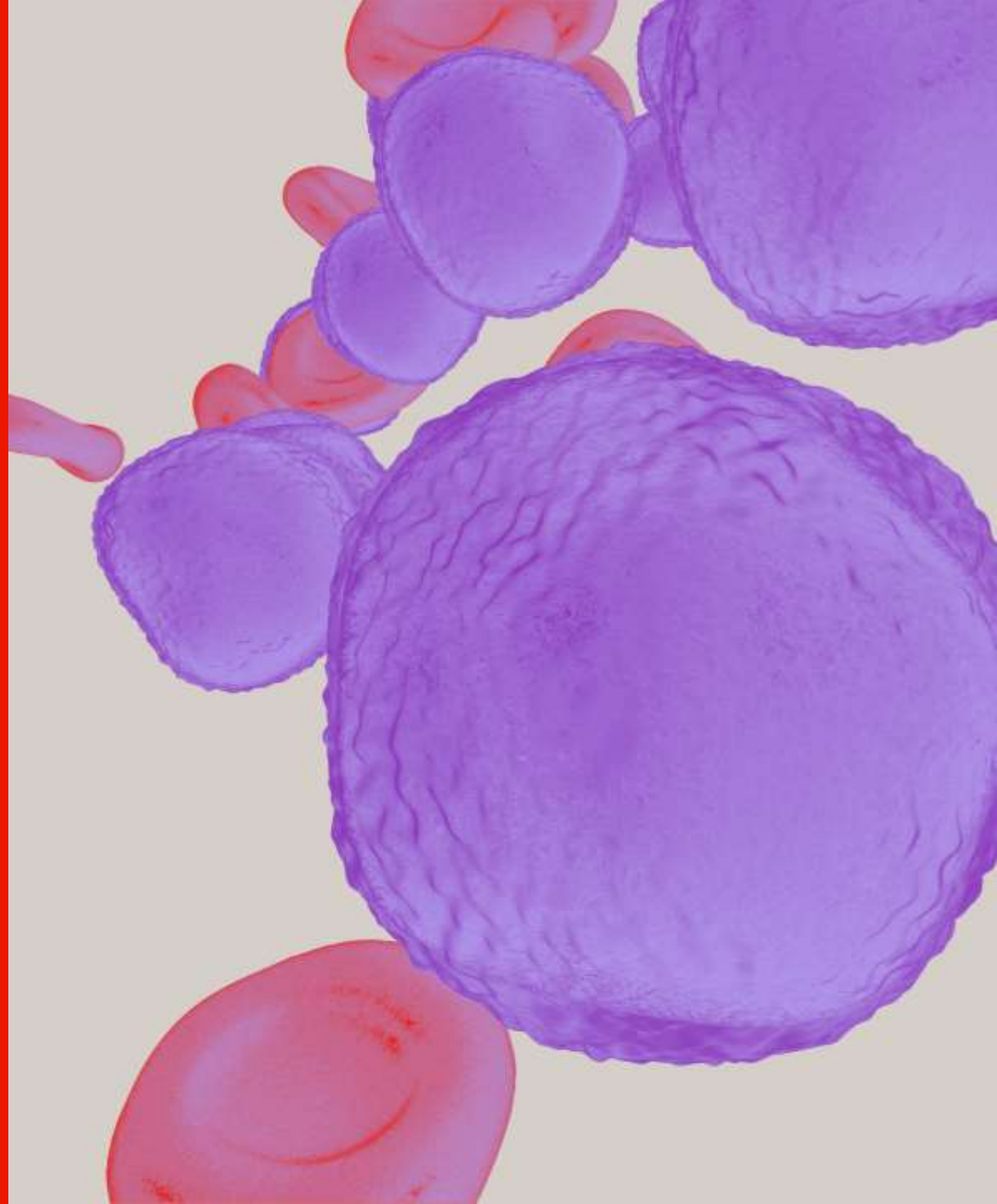
Reducing vein-to-vein time for cell therapy



Johnson&Johnson

4 December 2025, Utrecht

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Accelerating innovation worldwide

Bold collaboration across the healthcare spectrum

Viggo Van Tendeloo, PhD
External Scientific Innovation, Country Lead, Benelux

Johnson&Johnson

4 December 2025

Our business segments

Johnson&Johnson Innovative Medicine

Johnson&Johnson MedTech

We bring unique scientific and commercial expertise across Innovative Medicine and MedTech

Johnson&Johnson Innovative Medicine

- Immunology
- Oncology
- Neuroscience
- Cardiopulmonary
- Data science & digital health
- Discovery, product development and supply

Johnson&Johnson MedTech

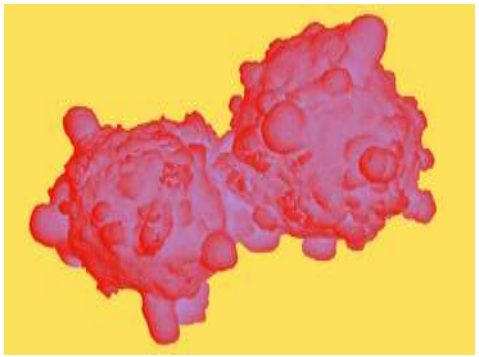
- Preparation, prevention, intervention, and recovery
- Technologies

Integrated healthcare solutions

- Interventional oncology

Addressing patient unmet needs

We're focused in areas where patient need is high, and our expertise is deep



Oncology

- Lung Cancer
- Prostate Cancer
- Bladder Cancer
- Colorectal Cancer
- Multiple Myeloma
- B-Cell Lymphoma
- Acute Myeloid Leukemia

Immunology

- Psoriasis
- Atopic Dermatitis
- Ulcerative Colitis
- Crohn's Disease
- Psoriatic Arthritis
- Rheumatoid Arthritis
- Maternal-Fetal Diseases

Neuroscience

- Schizophrenia
- Depression
- Myasthenia Gravis
- Alzheimer's Disease
- Geographic Atrophy

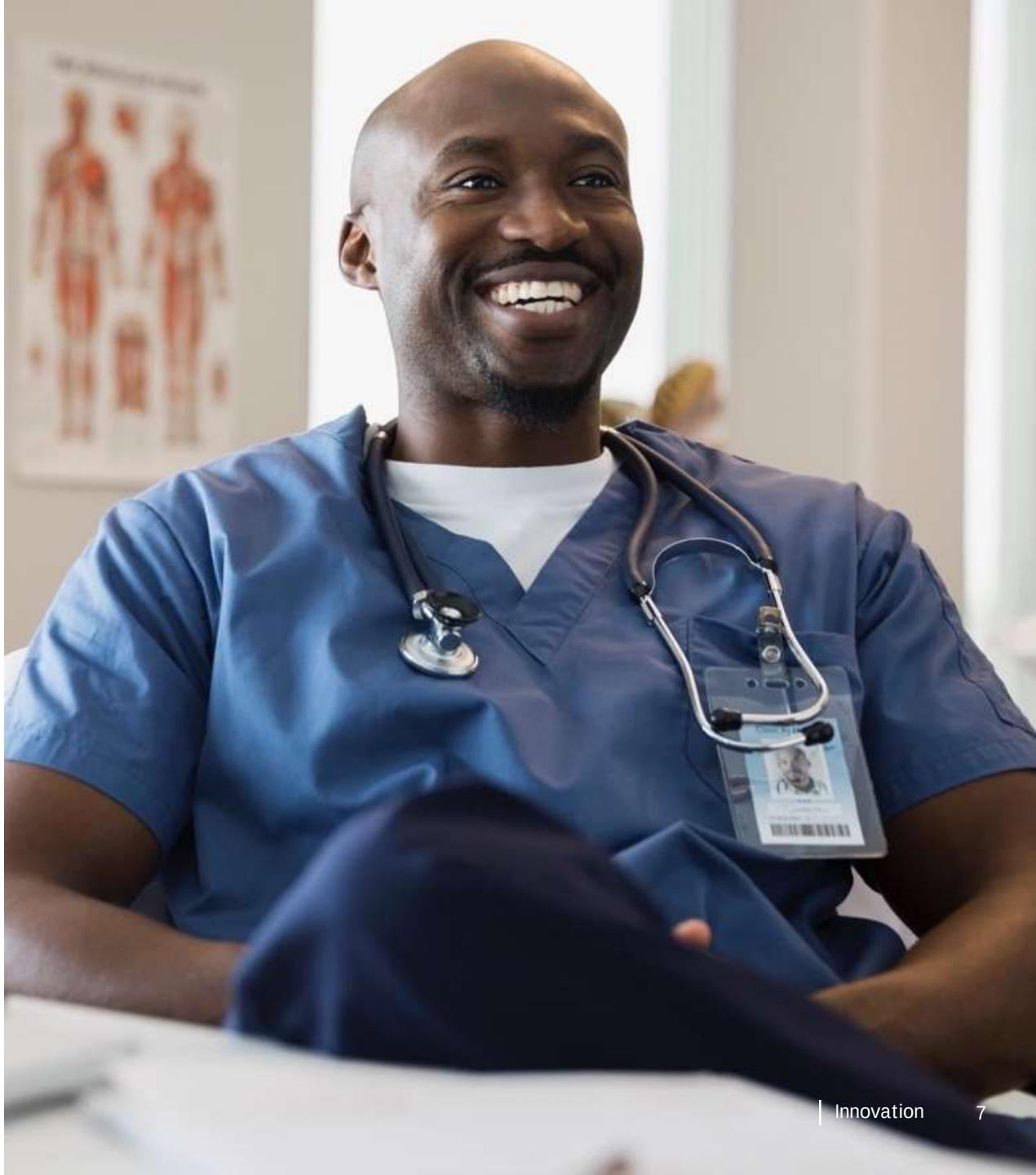
Select disease areas

- Thrombosis
- Pulmonary Hypertension

Our approach

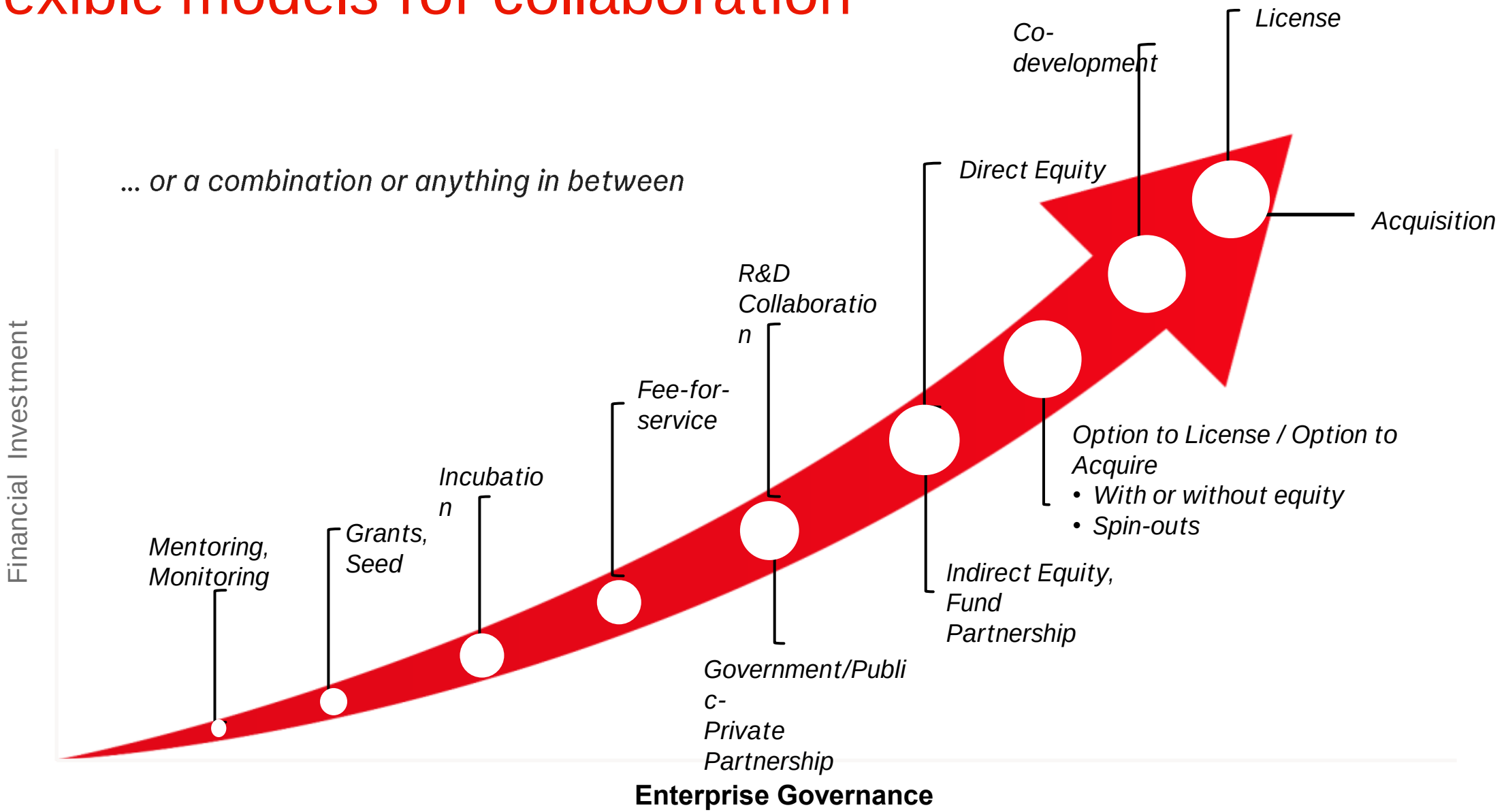
Focus on:

- Disease understanding
- Breakthrough therapies
- Early treatment
- Curative regimens



Advancing new healthcare solutions through collaboration

Flexible models for collaboration



Innovation acceleration & collaboration

Our global innovation partnering teams provide early-stage startups and life science innovators with a single point of entry to Johnson & Johnson. We aim to make it easy for collaborators to connect with us, all over the globe.

Wherever you are in the world, we're excited to connect.

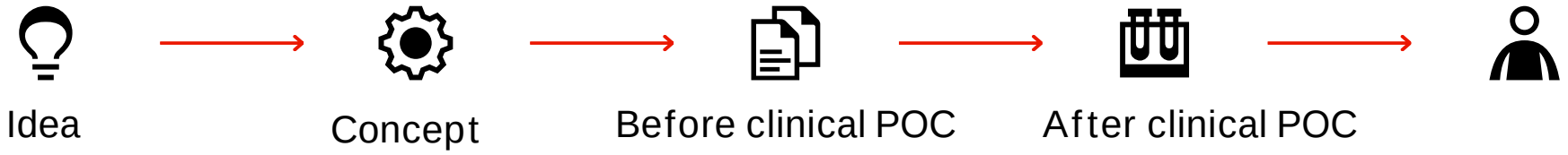
Locations across the globe in major life science and innovation hotspots

550+
licenses & collaborations since 2015 – Q4 2024(A)

$2.5B+
in license & collaboration upfront payments since 2015(A)

(A)Data from 2015-2024 for investments supported by Johnson & Johnson Innovation, Inc. Results have been recast to reflect the continuing operations of Johnson & Johnson.

We meet innovators where they are, supporting them at every step of the way



Access to J&J scientific and commercial expertise and our global network

Innovation Centers	Early-stage strategic R&D collaborations and licensing
JLABS	Incubation and 'killer experiment' collaborations
JJDC	NewCo creation & strategic venture investments
Business Development	Strategic collaborations and licensing Acquisitions Divestments and out-licensing

JLABS: Incubating & accelerating innovation

We offer the largest global network of open innovation ecosystems that enables and empowers emerging companies with knowledge, experience, partnerships, and venture connections across a broad healthcare spectrum.

Incubators

1,100+

companies, including current resident companies and alumni

350+

companies with at least one deal, strategic partnership or QuickFire Challenge award with Johnson & Johnson

QuickFire Challenges: crowdsource global innovation

100+ QuickFire Challenges launched

8,700+ applicants

260+ innovators

$30 million in grant funding

An innovative approach to help identify, empower and enable potential breakthrough healthcare ideas from innovators across the globe, QuickFire Challenges are designed to support innovators on their quest to advance scientific breakthroughs and build the healthcare system of tomorrow.

Innovators with ideas most strategically aligned to the respective QuickFire Challenge may be awarded any combination of grant funding, access to world-class lab facilities, programs and resources, and mentorship from industry experts.

Learn more and discover the latest opportunities at http://jji.jnj/challenges.

#MakeTheConnection

Meet up at local, regional and global partnering events.

Contact us and submit your ideas through our online challenges.

Visit our locations across the globe.

Explore our website and get to know our leadership.

Engage with us and our collaborators through social media.

J&J

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Follow us on Twitter
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Enabling scale in autologous CAR-T cell manufacturing with robotic automation

Dr Edwin Stone


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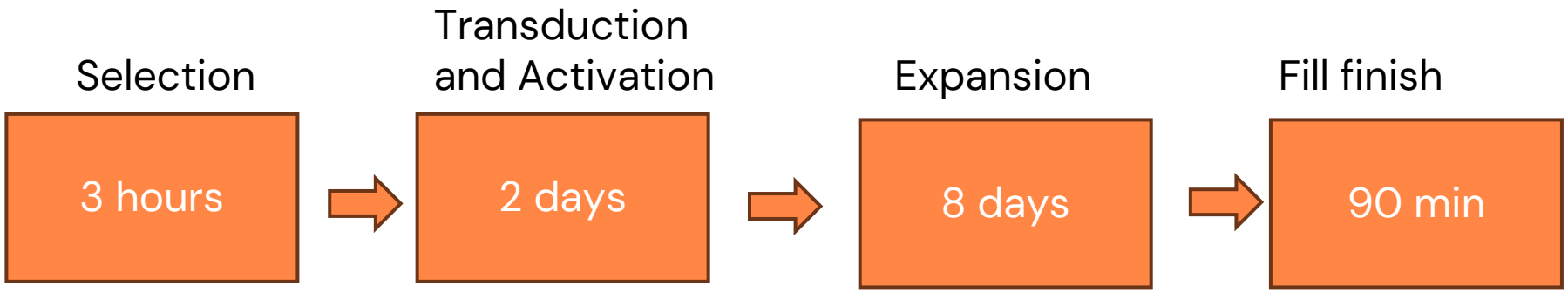
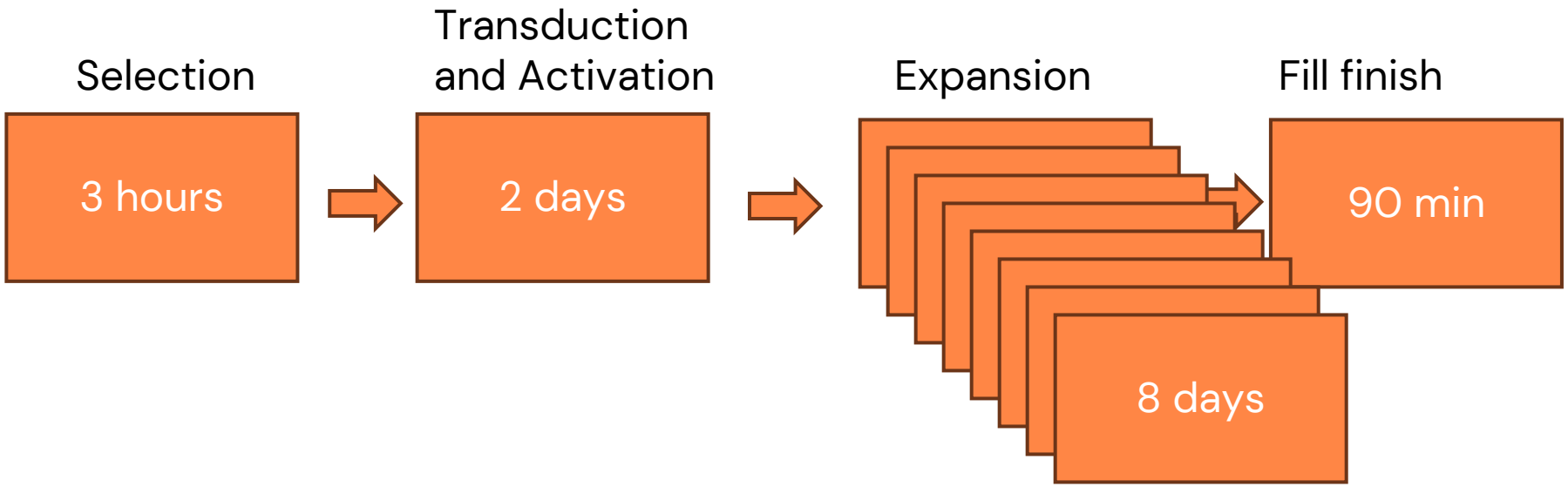
A process goes at the rate of the slowest process



First step is to create the best possible process

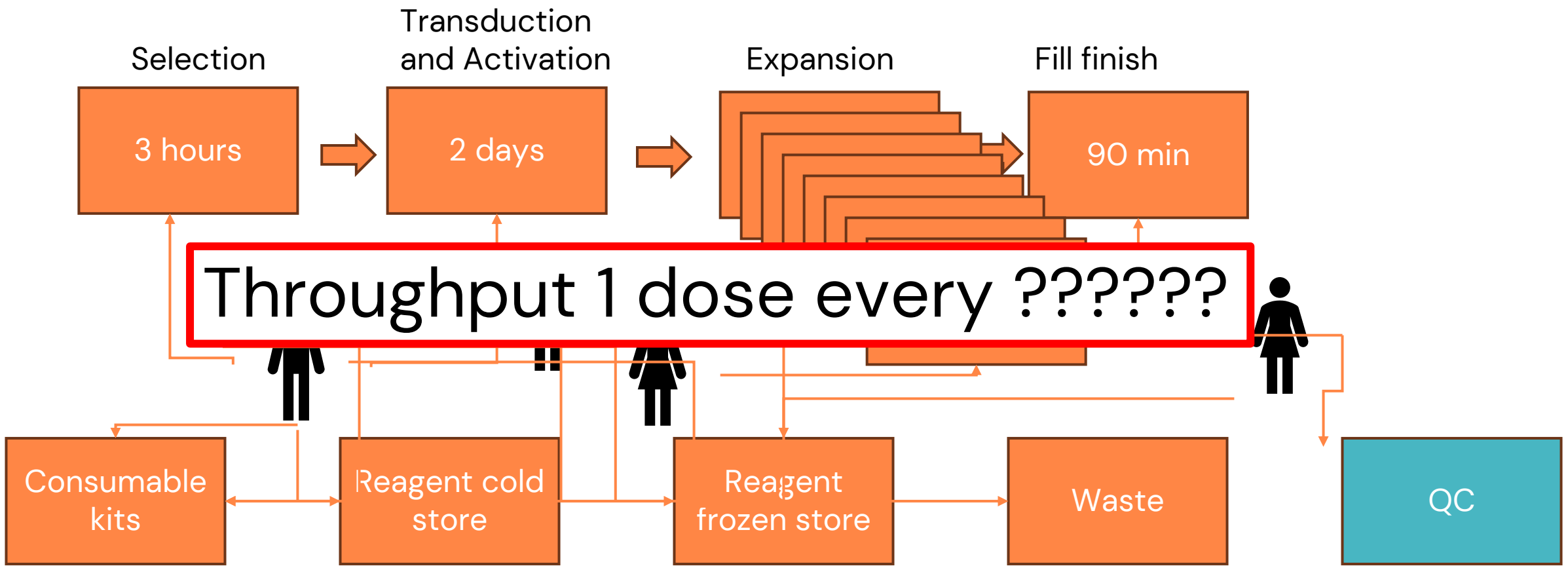
Throughput 1 dose every 8 days

Add capacity to the rate limiting step – 8 bioreactors



Throughput 1 dose every day

But this is a deterministic process, cell therapy is more complicated



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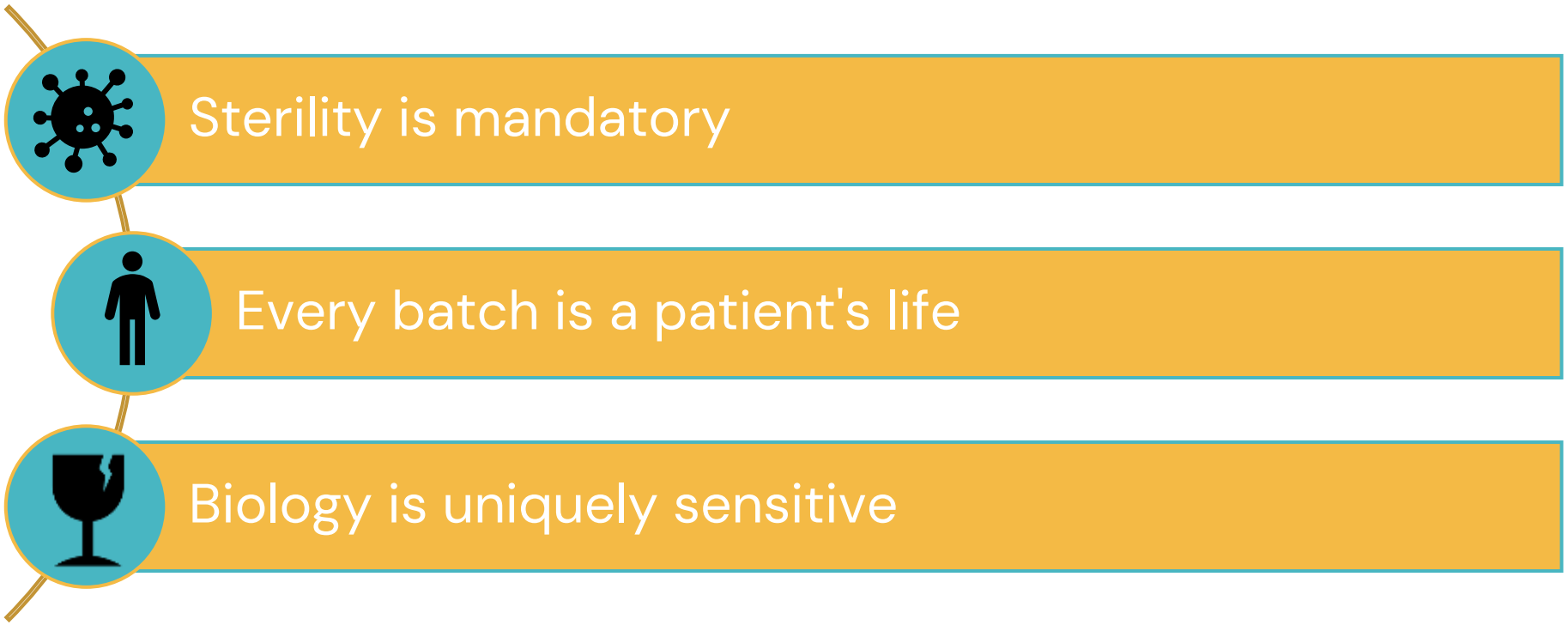
As well as limiting scale, people are driving high cost and variability

- These problems are not unique to cell therapy, but in other industries they have been solved
- Robotic automation has driven scale, quality and low cost
- Cellular Origins has adopted this backbone to solve the challenges of cell therapy manufacturing at scale

However, cell therapy has unique challenges



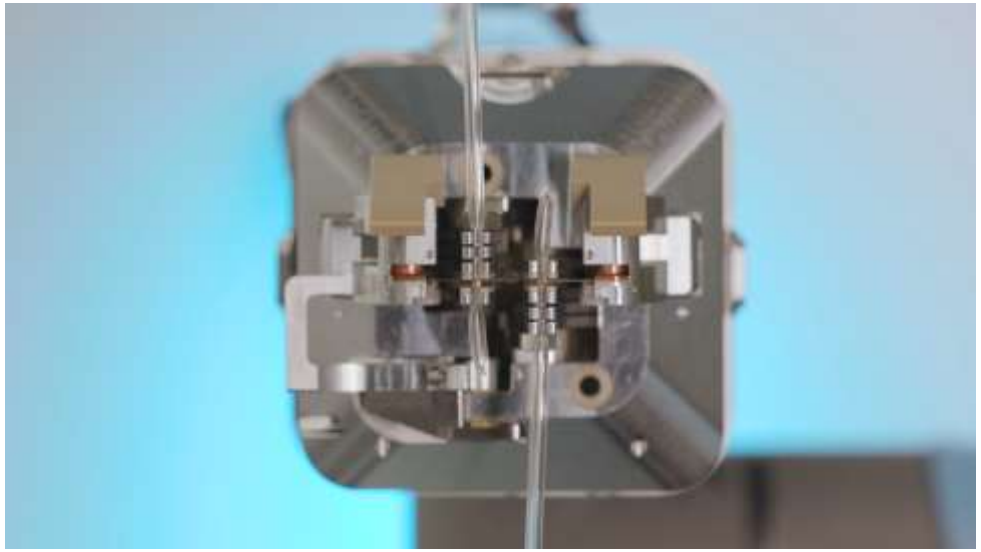
Sterile operation

Automated connection, fluid transfer and disconnection need to be automated

Regulatory Acceptance: 10,000s of sterile welds performed annually in approved processes

High Reliability: achieves extremely high success rates (>99.95% at 95% confidence)

Consumable Compatibility: unchanged consumables – key for therapy developers and tools providers



https://cellularorigins.com/resource/why-automated-sterile-tube-welder-technology-is-key-for-reliable-cell-therapy-manufacturing/

Designing for recoverability

Redundant capacity helps, but only if you can access is

Need to focus on recoverability and time to recovery across the automation stack including:

- **Factory level**: Operator access without impacting process
- **Robot level**: Mobile robotics and swappable end effectors allow for uninterrupted operation
- **Tool level**: Check of welds before opening fluid path and recovery if an issue

Factory simulation to prove timings, throughput and capacity

Biology is uniquely sensitive to the process

Proven tools, without change reduce the risk.

Biological test systems to demonstrate required biological performance

CATAPULT Cell and Gene Therapy
cytiva
FRESENIUS KABI
ThermoFisher SCIENTIFIC
ScaleReady
WILSONWOLF
STÄUBLI
3P innovation
MaxCyte
cellularhighways
xcellbio
AZENTA LIFE SCIENCES
autolomous
Biolife Solutions
biotechne
aglaris Ltd
KYTOPEN

cellularorigins

Facility builders have modelled ROI for robotic systems
Payback predicted to be <1yr

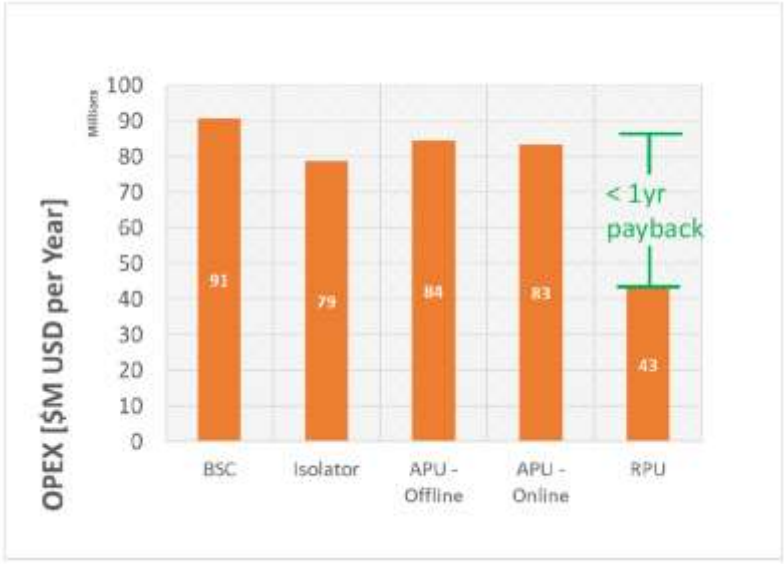
INTERPHEX | APRIL 1-3, 2025 JAVITS CENTER, NYC

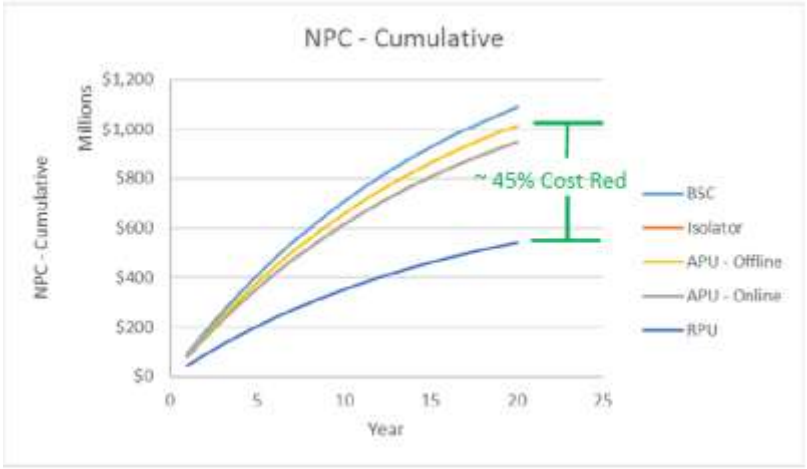
EXPERIENCE SCIENCE THROUGH COMMERCIALIZATION

Late Breaking
Cell Therapy Cost Analysis:
Technology Choices and Facility Design

Technology choices that reduce cost, improve scalability, and enhance robustness of supply.

Charles Heffernan, JD – Director of Advanced Therapies
Daryl Kern, AIA – Director of Architecture





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Conclusions

- Robotics is poised to eliminate the largest manufacturing bottlenecks (ie people)
- It drives reduced cost, increased quality and unlocks scale
- This can be achieved using proven cell processing tools and proven robotics
- Cellular Origins has deployed its first system already at a customer site in the UK and will be soon delivering to others around the world

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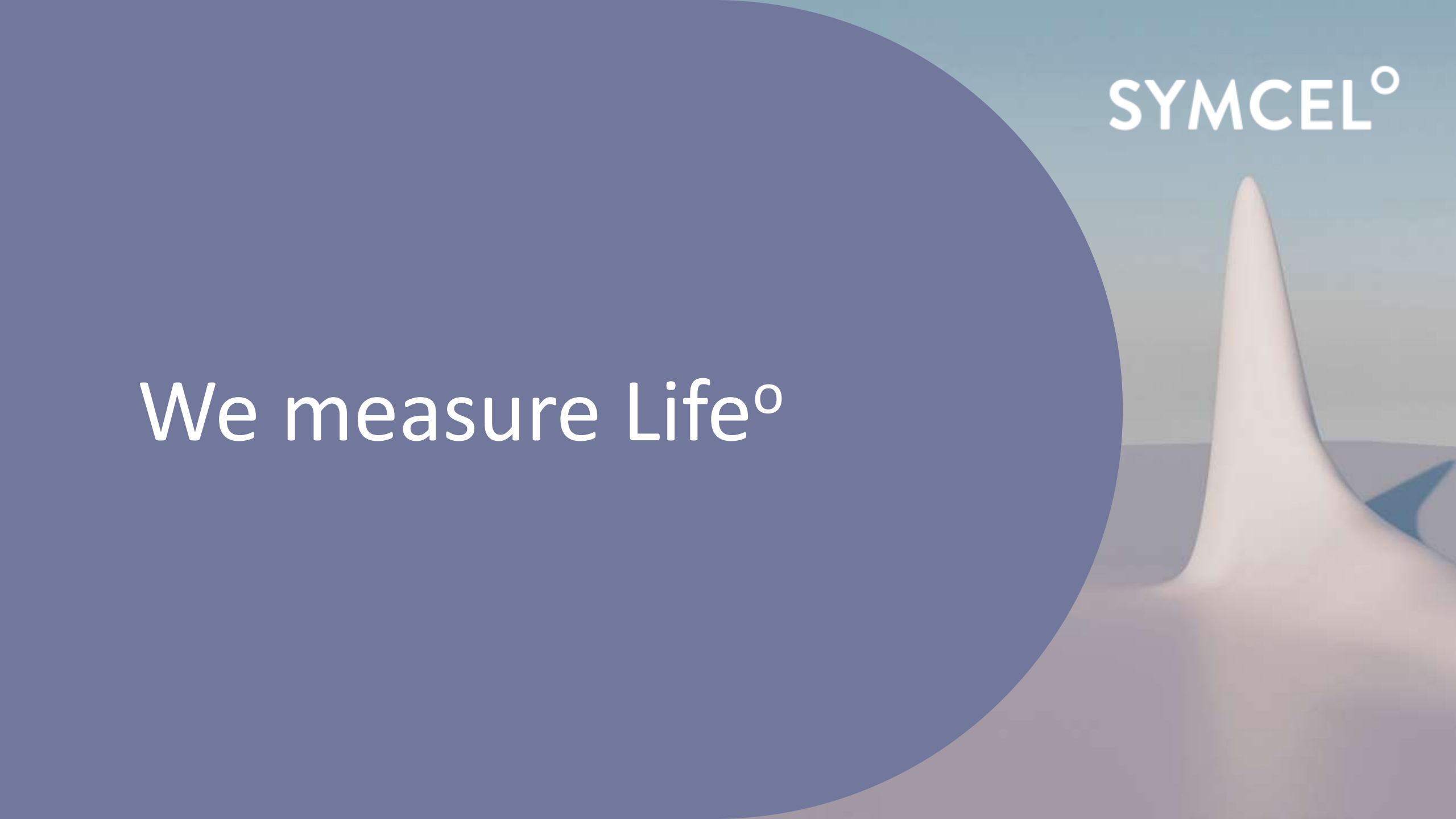
We measure Life°



Advancing rapid sterility testing in cell & gene therapy

Jesper Ericsson, CEO

jesper.ericsson@symcel.com

SYMCEL

MASTERS OF BIOCALORIMETRY

- Medtech company, global leaders in biocalorimetry
- 40 experts from 17 nationalities with 16 PhDs
- First microcalorimeter repurposed for biology
- Direct metabolic readout with unparalleled speed, simplicity, sensitivity, and specificity
- First commercial application with rapid sterility testing for cell and gene therapies

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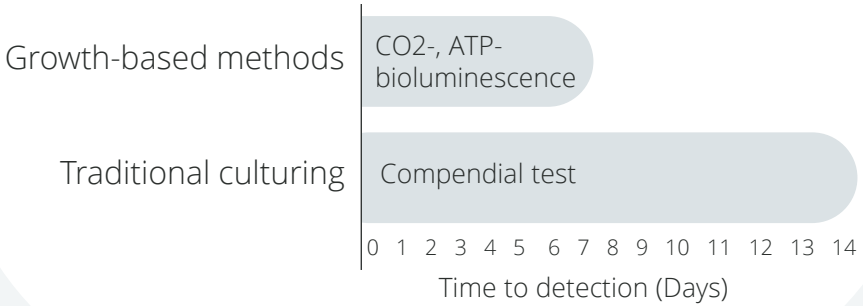
Release testing – sterility is the longest assay

Critical to shorten for reduced vein-to-vein time



Current methods too slow for ATMPs

- Generally 7-14 days
- Inhibition with product matrix
- Challenges with molecular methods
- Several manipulation steps

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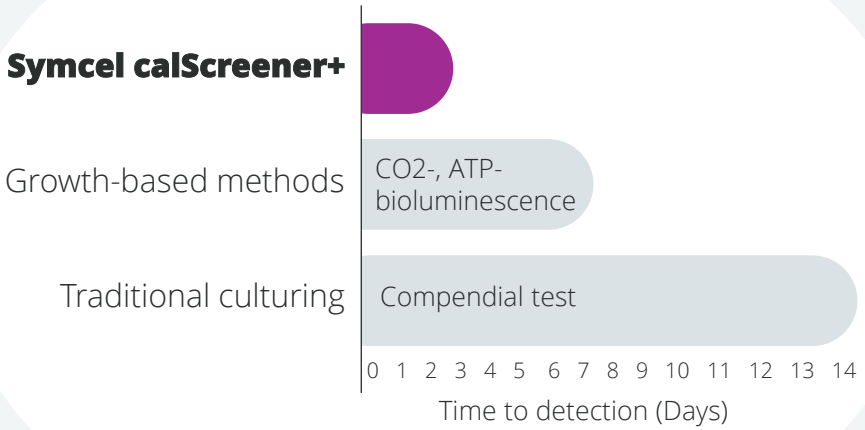
Symcel rapid sterility cuts time to <3 days

Faster product release, reduced cost & complexity and faster patient access



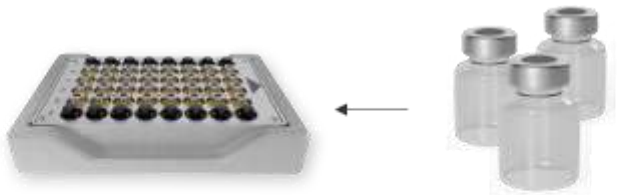
Symcel's solution

- **Results in <3 days**
- Continuous phenotypic monitoring
- Non-destructive measurement
- Direct inoculation of product
- High sensitivity, LOD 1.5 CFU

SYMCEL

Introducing the calScreener+

Next-generation sterility testing



calPlate™
for 32 samples

Disposable glass vial
with crimp cap

Validation strategy: Assay Comparison

	compendial	calScreener+
Assay type	Growth based	Growth based
Culture medium	TSB and FTM	TSB and FTM
Incubation temperature	25 °C and 35 °C	25 °C and 35 °C
Assay length	14 days	**3 days**
Readout	Visual inspection End point	**Automated** detection of metabolic activity in real-time

Through **calView** software based on custom algorithm

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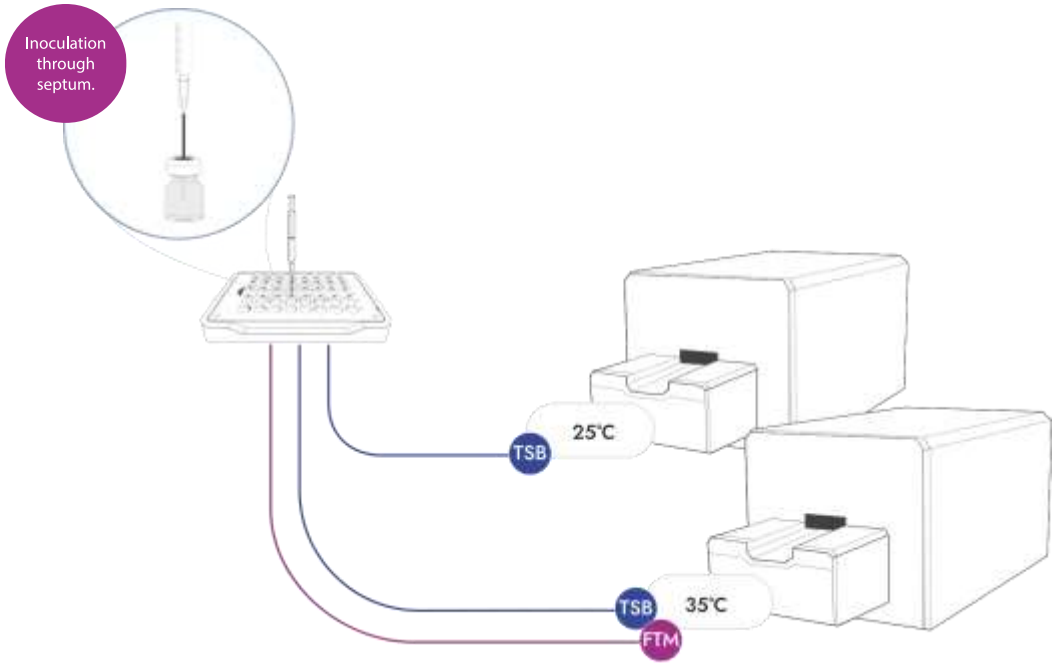
Introducing the calScreener+

Direct inoculation



Dual system growth assay

- Two calScreener+ units
- 20-40°C temperature range

Meet regulatory compliance

- 21 CFR part 11 compliance supportive software
- IQ/OQ/PQ/DQ

Throughput capability

- Up to 2 x 32 samples
- Disposable glass vials (50 µl to 550 µl)

Premium Support Plan

- Premium application support
- Maintenance and service

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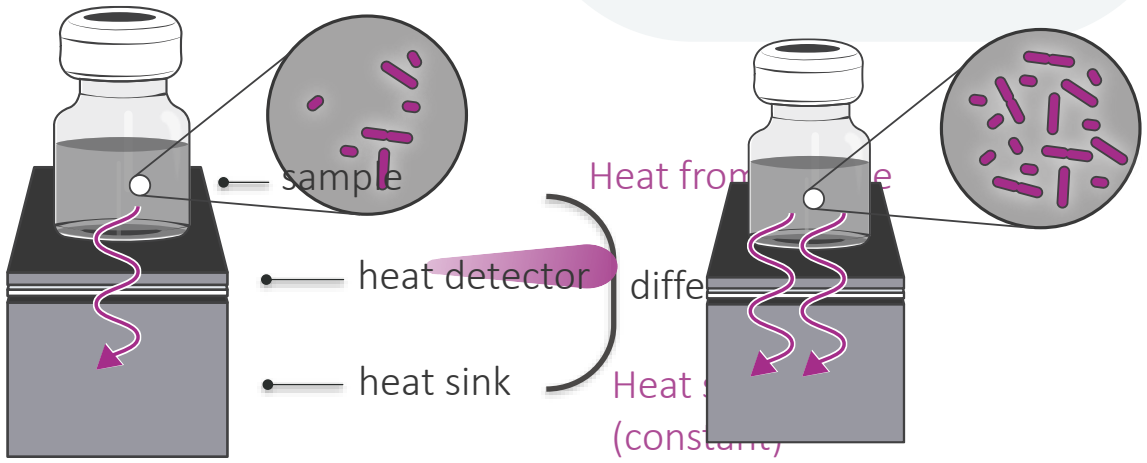
Introducing the calScreener+

Biocalorimetry principle

Changes in heat (flow) are detected and monitored with precision in the µW range.



All living cells are metabolically active and metabolic processes produce heat.

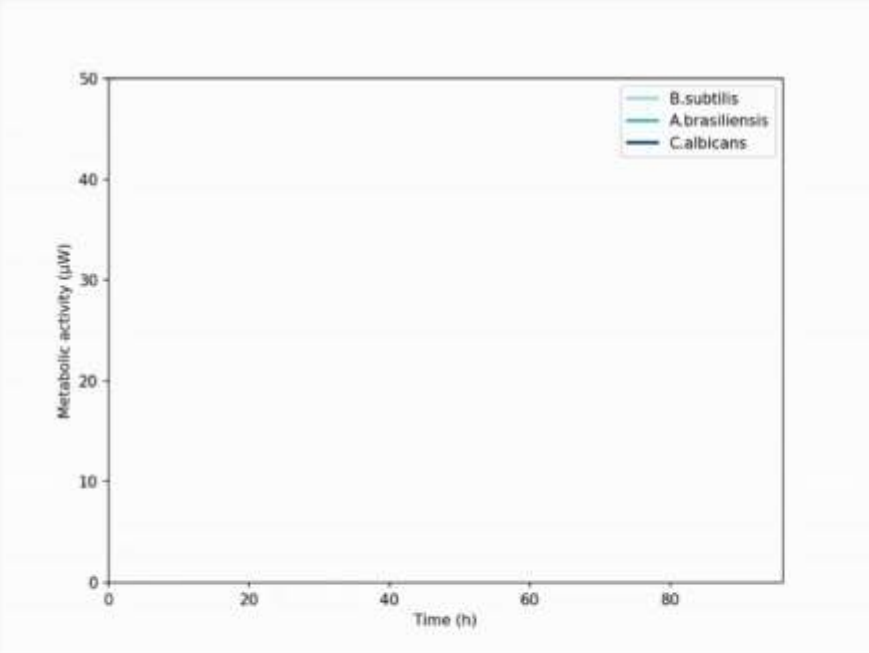
Proliferating microbes are highly metabolically active.

Offers a more direct growth based microbial detection method than assays based on sequential pH change, CO_2 increase, and color change steps.

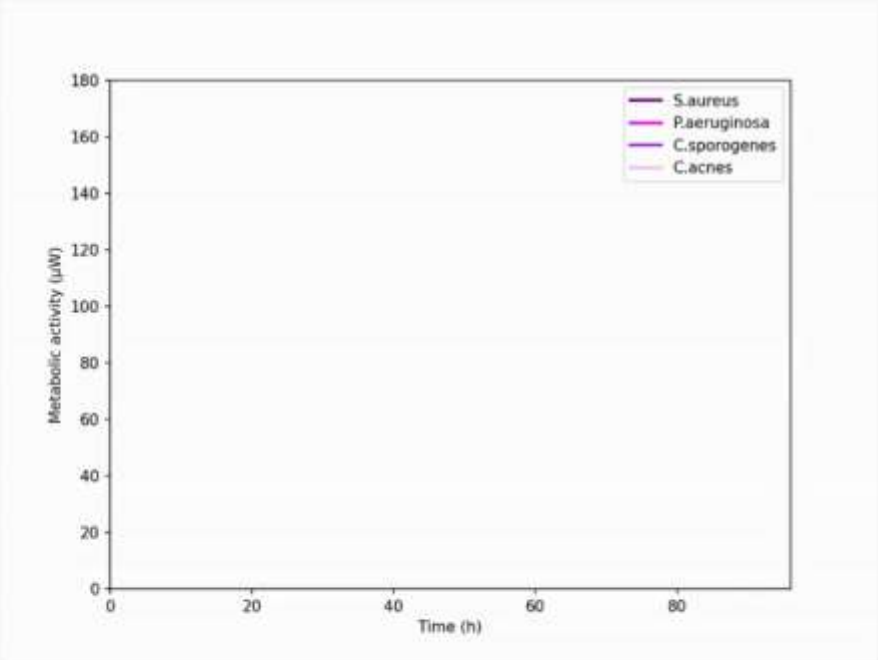
Continous microbial growth detection

Distinct heat-flow signal in contaminated samples

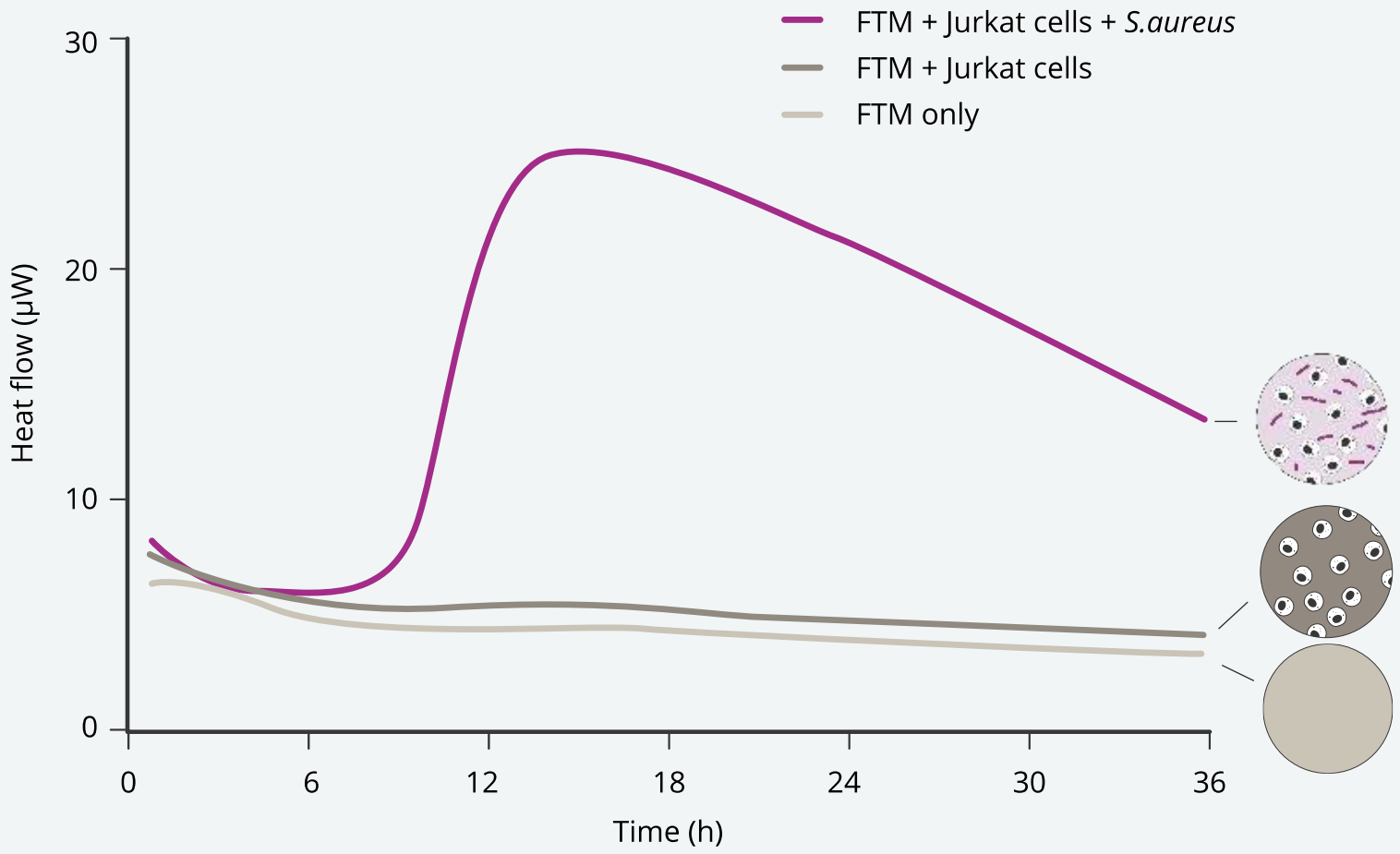
TSB 25°C



FTM 35°C

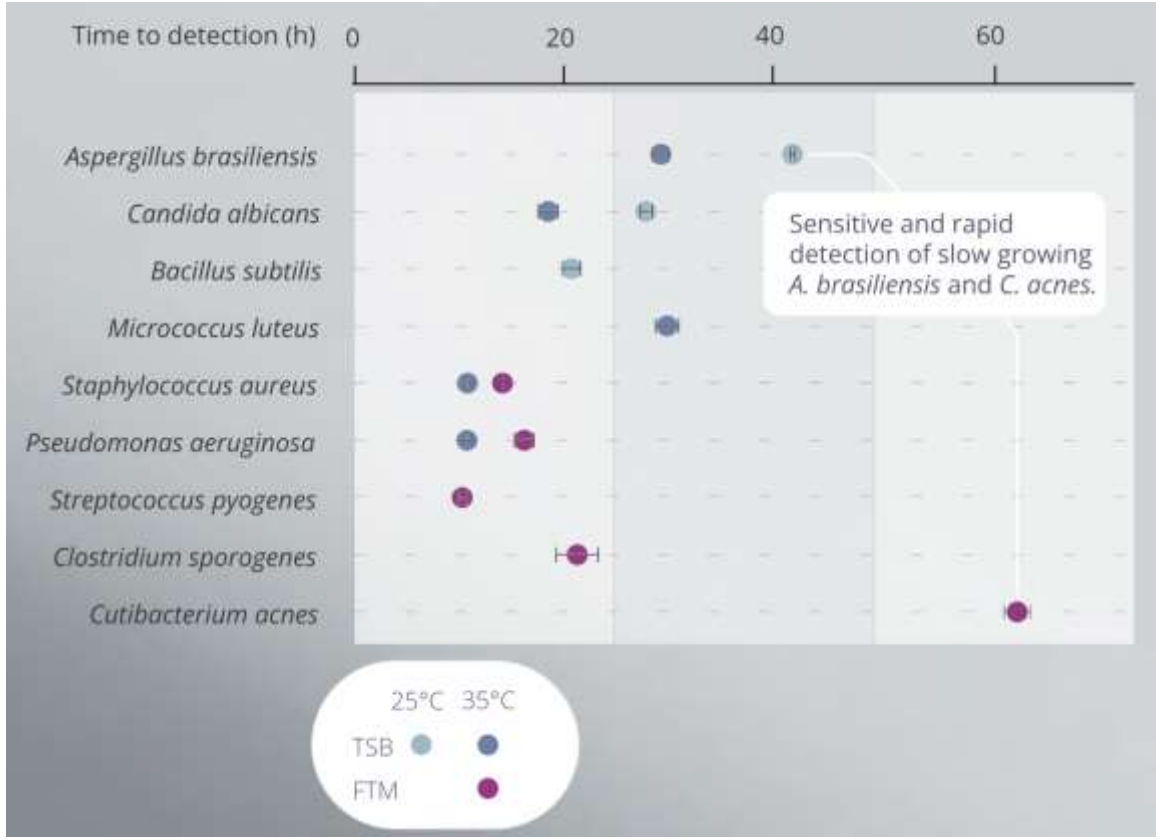


Microbial detection in complex cellular matrices

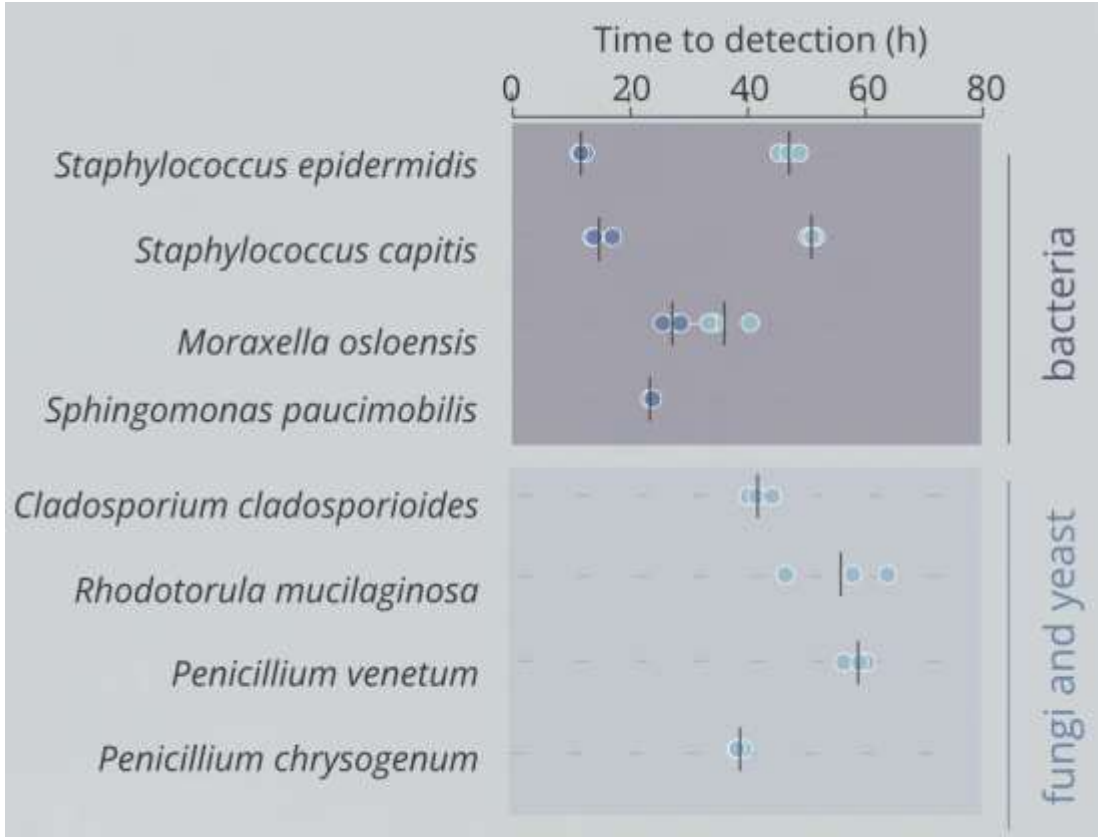


Detection in <3 days of key organisms

9 European Pharmacopoeia strains in <10 CFUs



Organisms in different manufacturing environments, <10 CFUs



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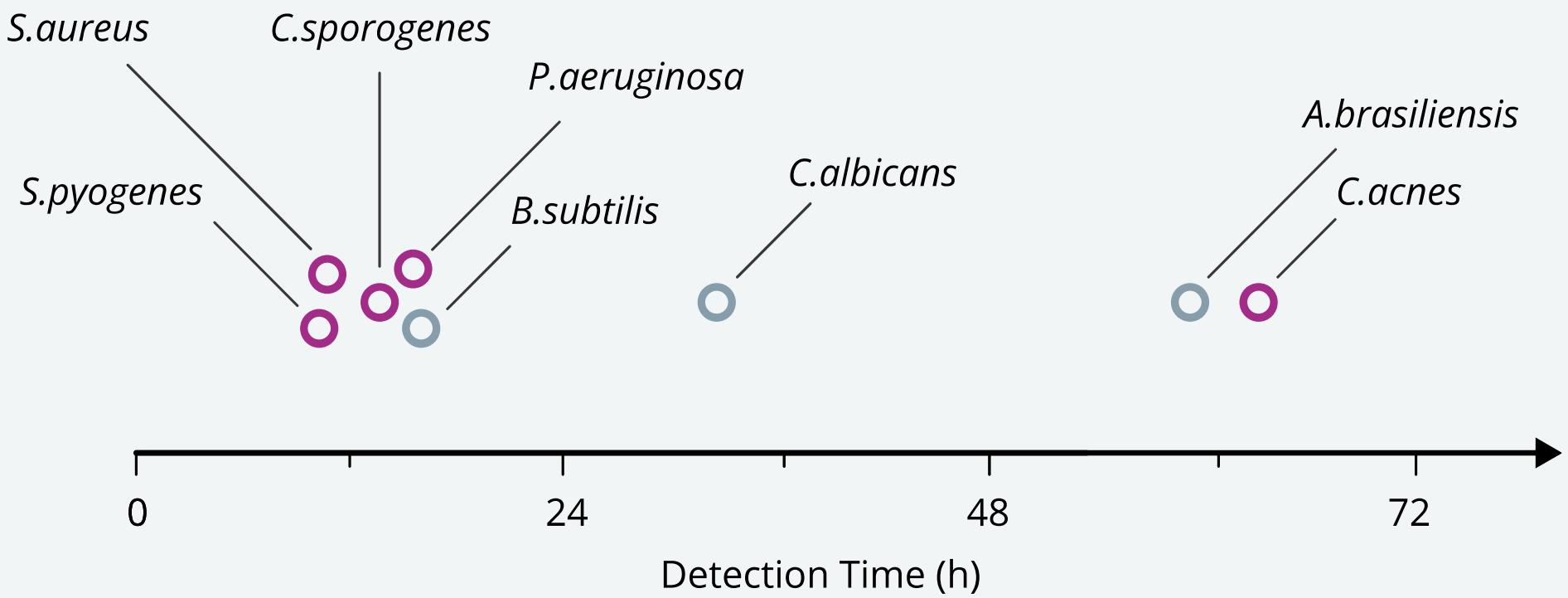
Customer case study – 63 hour detection

T-cell progenitor therapy product



Product spiked with CFU < 5, 1:1 product:media ratio

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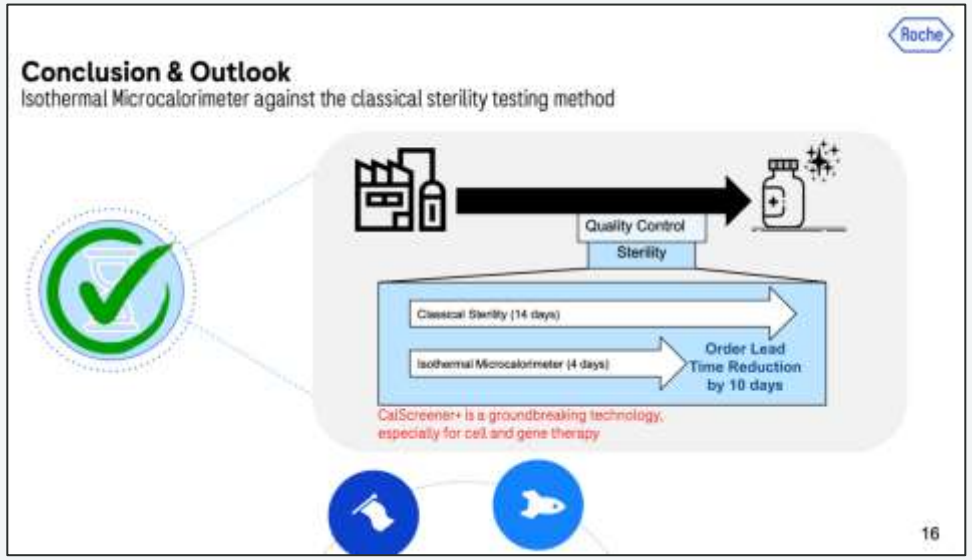
Roche Diagnostics evaluation

Independent evaluation, presented at ECA microbio in May 2025

Time to results cut by more than 70% compared to compendial sterility methods

- Consistent detection across a broad panel of microorganisms.
- TTD 56 - 63h for C. acnes and P. aeruginosa in monoclonal antibody product
- TTD < 76h for A.brasiliensis, C.acnes, C.albicans and P.aeruginosa in HEK cell culture



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J&J strategic R&D collaboration

Deliver a validated, GMP-compliant test that cuts release time to under 3 days — improving manufacturing efficiency

Presentation last week at Pharmalab – 50% time cut vs BacT

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Ongoing development

Large volume automated solution

- **Fully automated system** – from sample loading to result interpretation
- **30 patient sample capacity** with **dual temperature**
- **10 mL disposable glass vials** prefilled with growth media for **direct inoculation**
- **Random-access** workflow with minimal hands-on time
- **72-hour presence/absence detection** with continuous real-time monitoring

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Conclusions

- **Rapid phenotypic sterility testing**
  calScreener+ detects challenging organisms, including slow-growers, within ≤3 days using direct metabolic readout in product

- **Validation supports non-inferiority**
  Ongoing USP/Ph. Eur. aligned studies show high specificity, LOD, and robust performance across key variables

- **calScreener+ ready for CGT implementation end 2025**
  - **Large volume system** - early customer evaluations late 2026

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CONTACT

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