MIDA Biotech

A fully owned subsidiary of Orgenesis inc.

TECHNOLOGIES FOR AUTOLOGOUS IPSC PROCESSING

Malin Stridh

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Name	Mida Biotech B.V.
Founded	2021
Lab opened	January 2022
Location	Leiden, NL

Our mission

"Incorporating cutting edge science into industrial solutions for advanced therapies"

INNOVATION IS KEY

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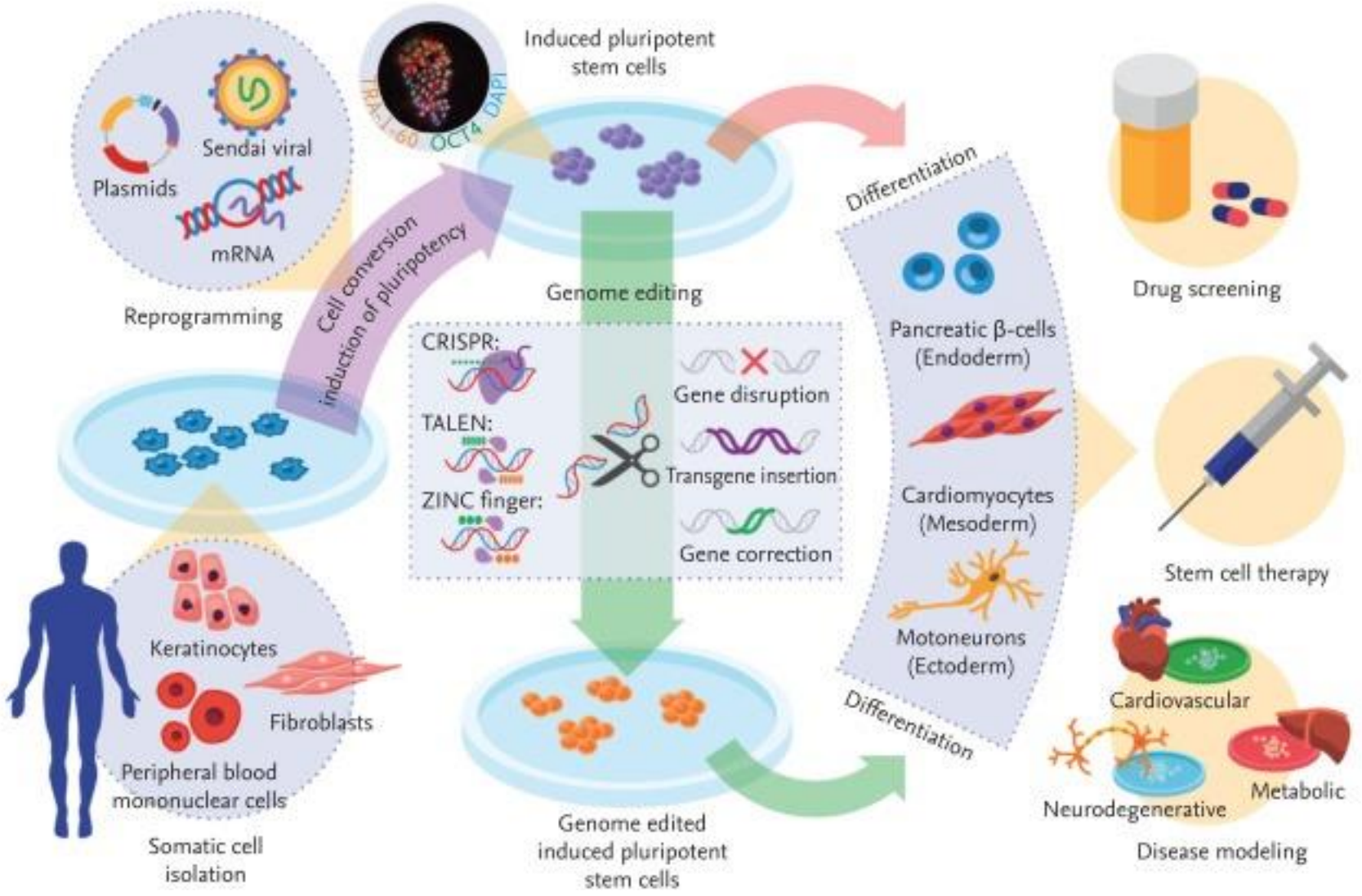
Our stem-cell platform Laboratory is located in Leiden Bioscience Park (LBSP), the largest Life Sciences and Health cluster in the Netherlands and one of Europe´s leading innovation hubs

Home to over 152 companies LBP fosters a collaborative ecosystem of innovative companies, research institutes and academia

LBSP´s environment provides MIDA with great access to human talent, innovation culture and scientific knowledge

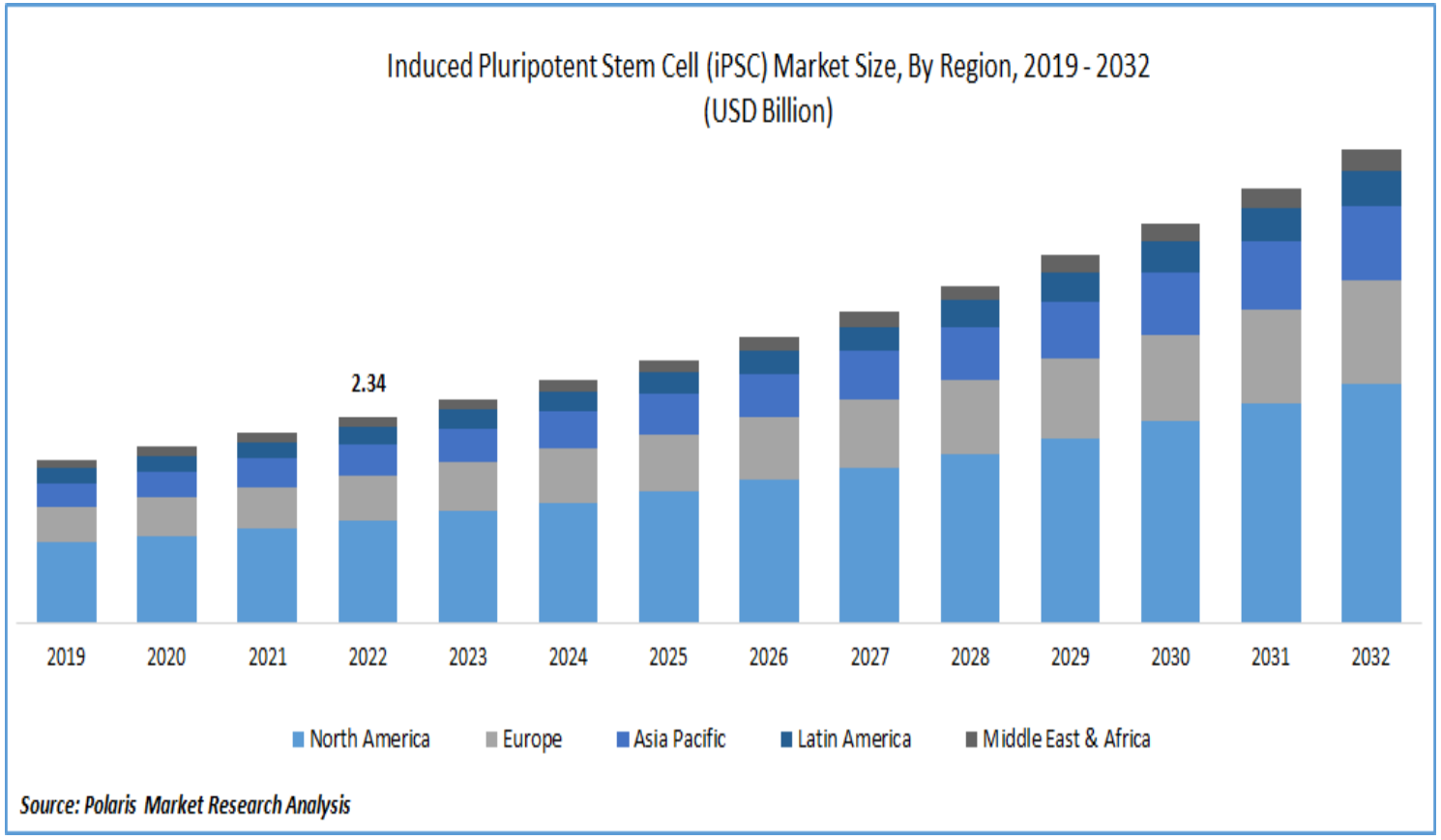
The iPS (stem) cell promise



IPSC MARKET SIZE

The global iPSC market was valued at USD 2.34 billion in 2022 and is expected to grow at a CAGR of 8.7% during the forecast period

Patient-specific iPSCs and directed iPSC differentiation are key industry trends that will fuel market growth



Allo vs Auto

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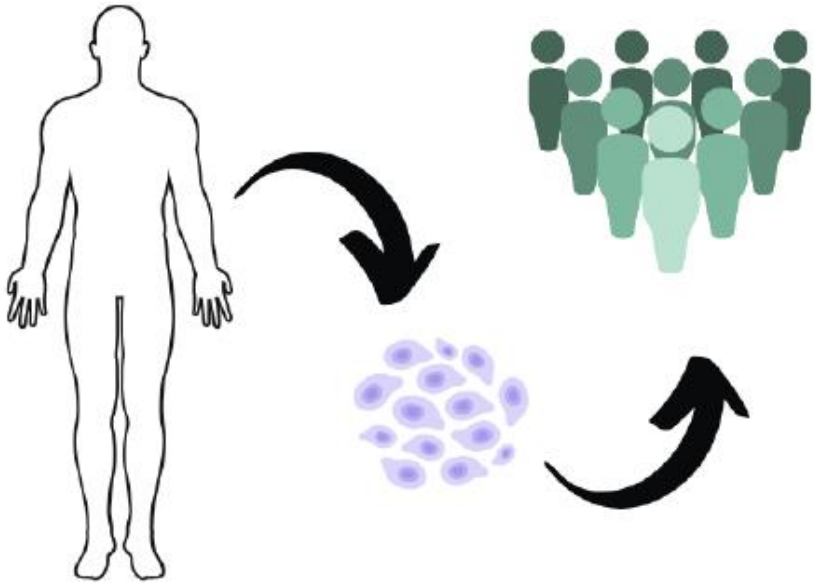
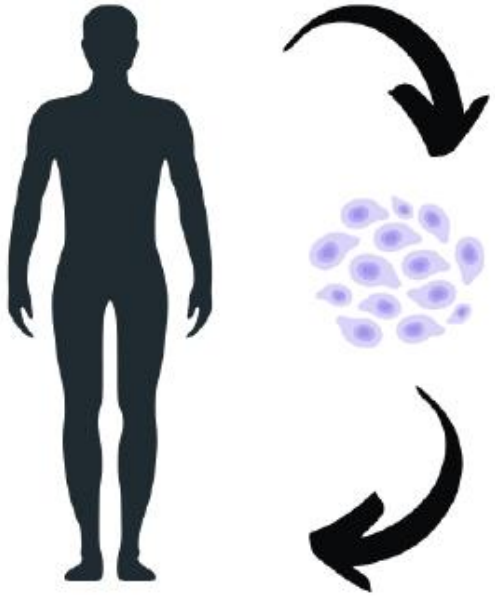
Allogeneic cell therapy



Autologous cell therapy



WHAT'S CURRENTLY HOLDING BACK IPSC-BASED PRODUCTS?

- No scalable production solution on the market
- Lack of standardization due to dependence on stem cell experts
- Need for immune-suppression when using allogeneic cells
- Genomic instability of iPSCs

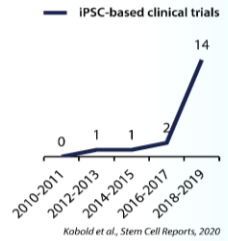
Automated industrial solutions are urgently needed!

Funded by the European Union

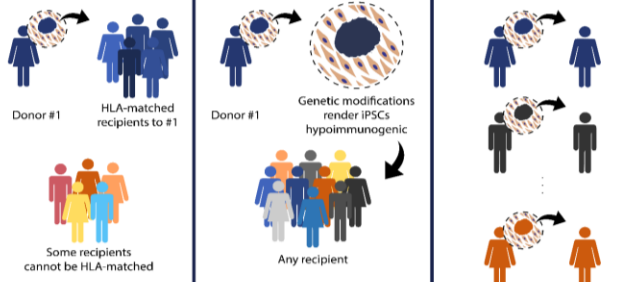
AUTOLOGOUS IPSC PRODUCTION

Proprietary technology for automated autologous iPSC production using microfluidics and state-of-the-art AI

The challenge



Despite the increasing number of iPSC-based therapies in clinical trials, **the immunological barrier between donor iPSCs and tissue recipients remains a major bottleneck in cell manufacturing** hindering the progression of stem cell-based therapies.



Problems:

- Immunosuppresion required
- Lack of universality

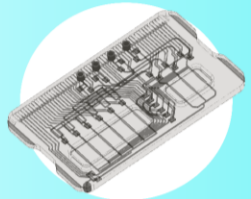
Problems:

- Incompatible with specific therapies
- Contagious cancers

Problems:

- Cost-ineffective
- Labour intensive
- Time-consuming

Technological breakthroughs



Pioneering microfluidic device for culturing and reprogramming of fibroblasts

- Small volumes
- Automatic
- High throughput

Novel next generation sequencing-based colony quality indices

- In-depth characterization of pluripotency, differentiation and genetic variability

AI-powered module for morphology-based quality control of iPSCs

- Deep Neural Networks
- Efficient classifiers

Ultimate goal

Development of AiPSC Vision and MorphoQC for a **fully automatized** platform for **GMP-compliant manufacturing** of **autologous iPSC lines**

AiPSC Vision

AiPSC MorphoQC

Reliable.
Errorless standardized iPSC manufacturing

Cost-effective.
Downscaled closed-system for iPSC manufacturing

Automatized.
Powered by AI models trained with next generation sequencing data

THE MIDA SOLUTION

AiPSC Vision: closed system for automated manufacturing and time-lapse imaging of autologous iPSCs within disposable microfluidic chambers

AiPSC MorphoQC: AI driven, image-based quality control and colony selection module for iPSC manufacturing for clinical and research purposes

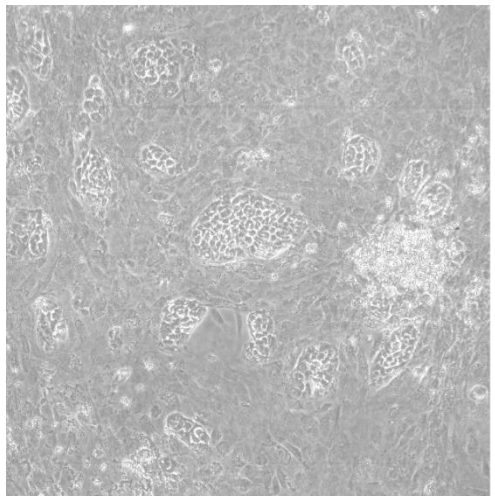
Comparison of AiPSC to the current state of the art for autologous iPSC manufacturing.

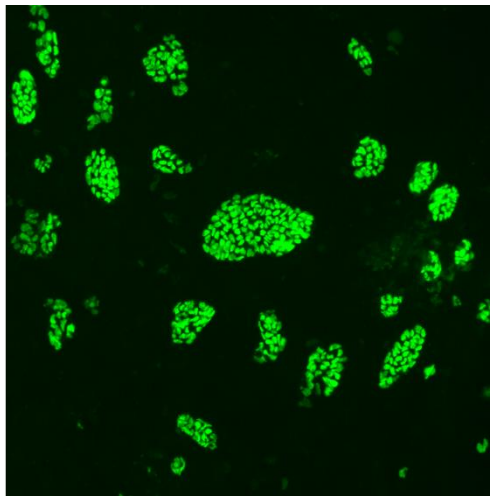
	Current state-of-the-art for autologous iPSC manufacturing	Autologous iPSC lines manufactured by AiPSC
Production time	> 6 months	Substiantially faster, expected to take ~ 2-3 months • Increase in efficiency and throughput
Manufacturing cost	~ 500.000 €	Expected to be ~ 5-10.000 € • Reduction of reagent cost • Reduction of workload
Number of handling steps for reprogramming/ amount of workload	Multiple handling steps (> 20) Heavy workload	only 2 manual steps: • Dissociation and injection of fibroblasts • Picking of colony selected by AI Light workload
Reproducibility	Manual handling is prone to errors Great variation between stem cell expert	Fully automated reprogramming solution Standardized and highly reproducible system

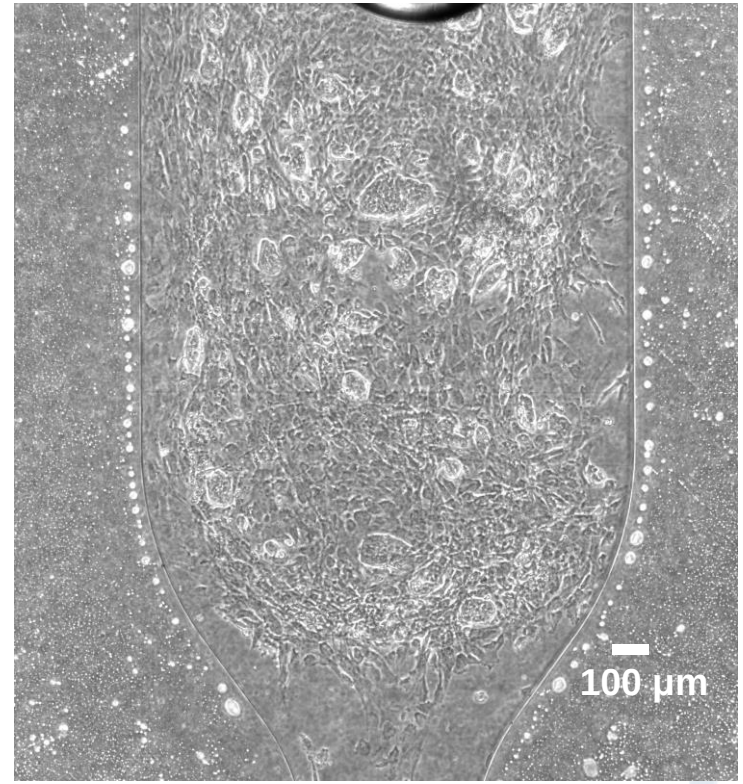
AUTOLOGOUS FIBROBLAST REPROGRAMMING

Our AiPSC platform utilizes custom microfluidic chambers to

- Scale down reagent volume
- Enhance process automation
- Increase standardization







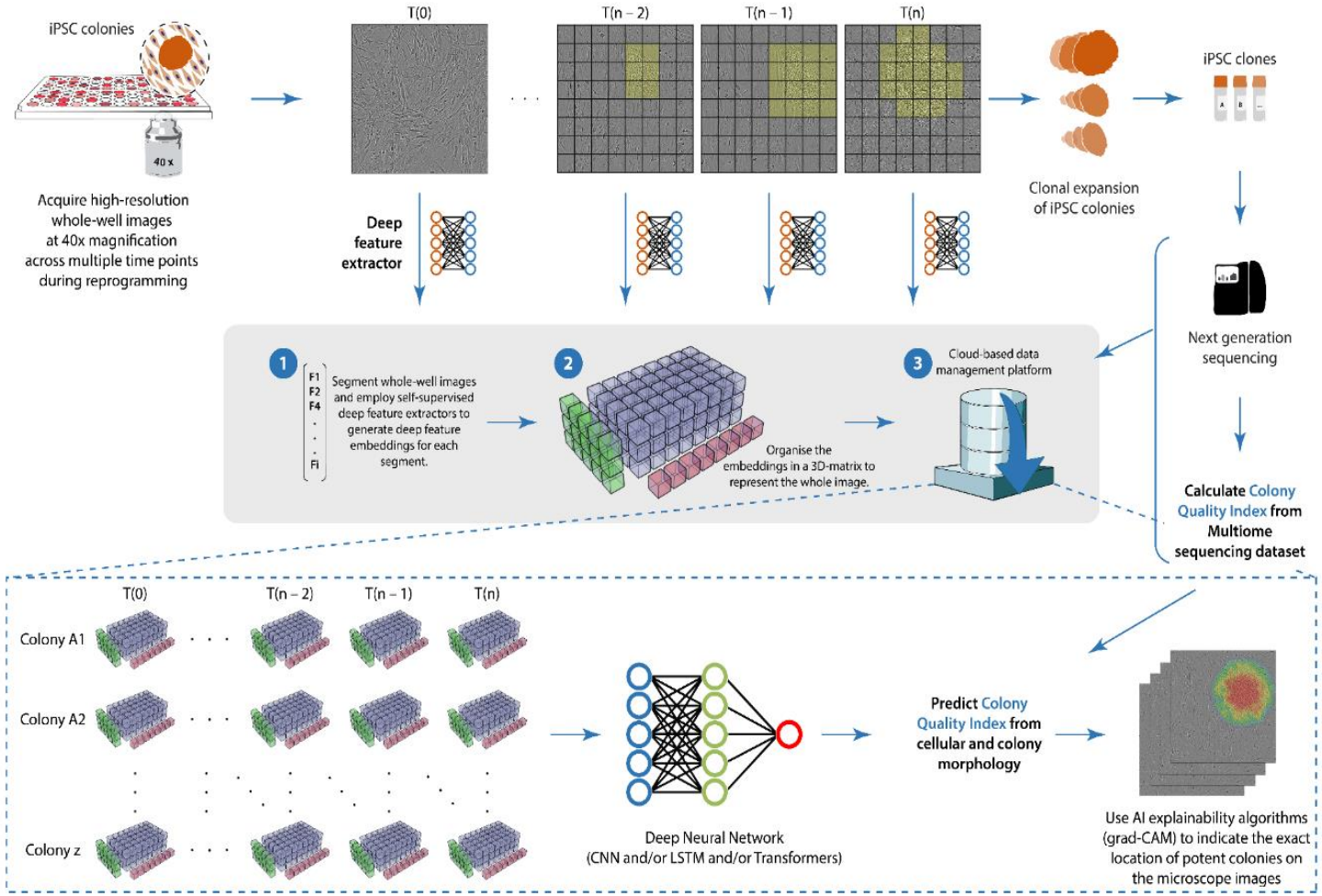
Reprogrammed fibroblasts in the microfluidic chip stained for Oct4

AI-driven QC module

Supervised learning on gigapixel time-lapse images for the first time in the domain of iPSC processing to predict the colony quality.

State of the art deep neural networks is used to extract and combine information from time-lapse images to predict pluripotency, specific differentiation potentials and genetic abnormalities.

The use of the AI-driven QC software will allow for ***standardization and higher precision*** when selecting colonies to expand, thus ***minimizing batch failure, cost and production time***.



COLONIES QUALITY CLASSIFICATION PIPELINE

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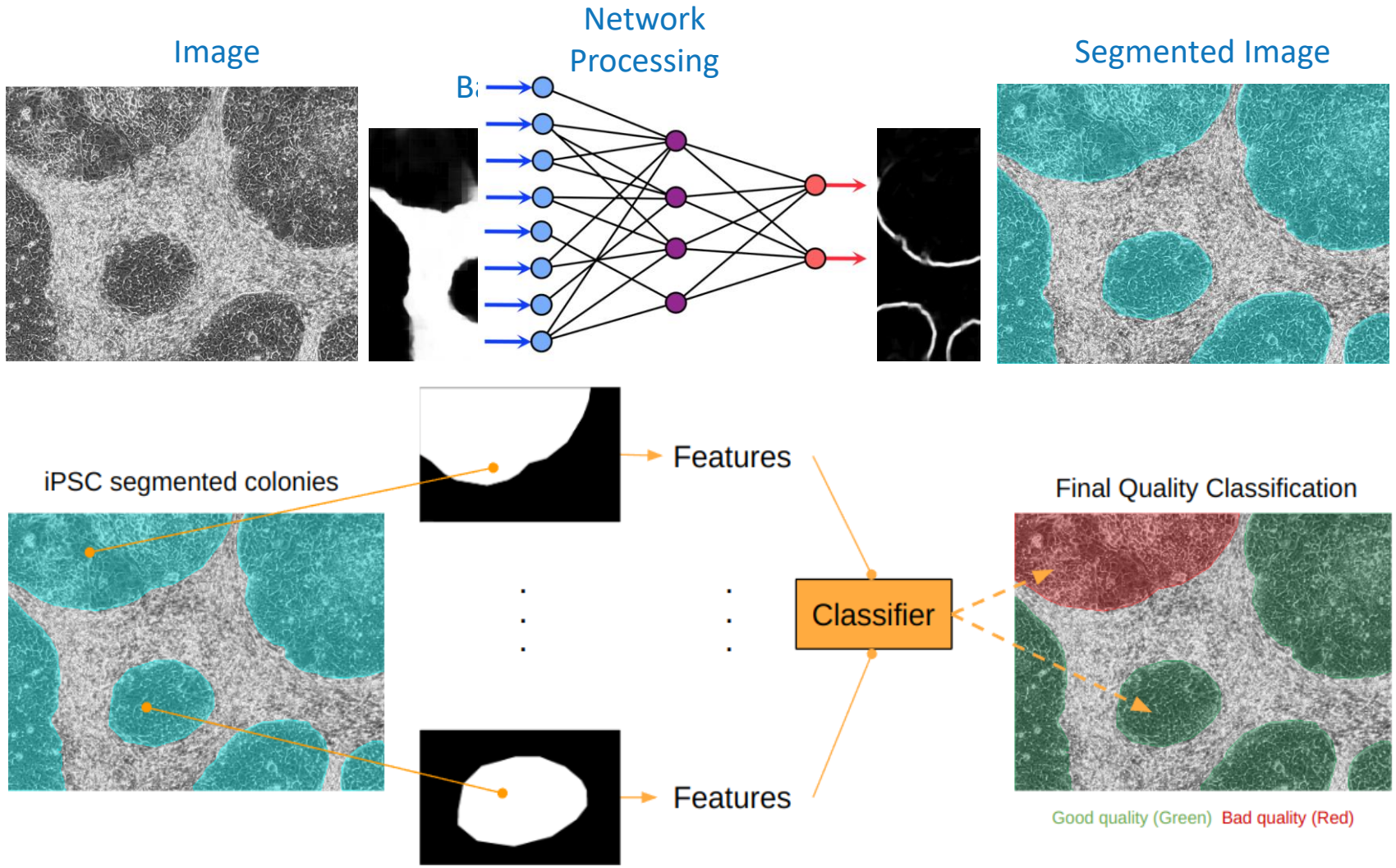
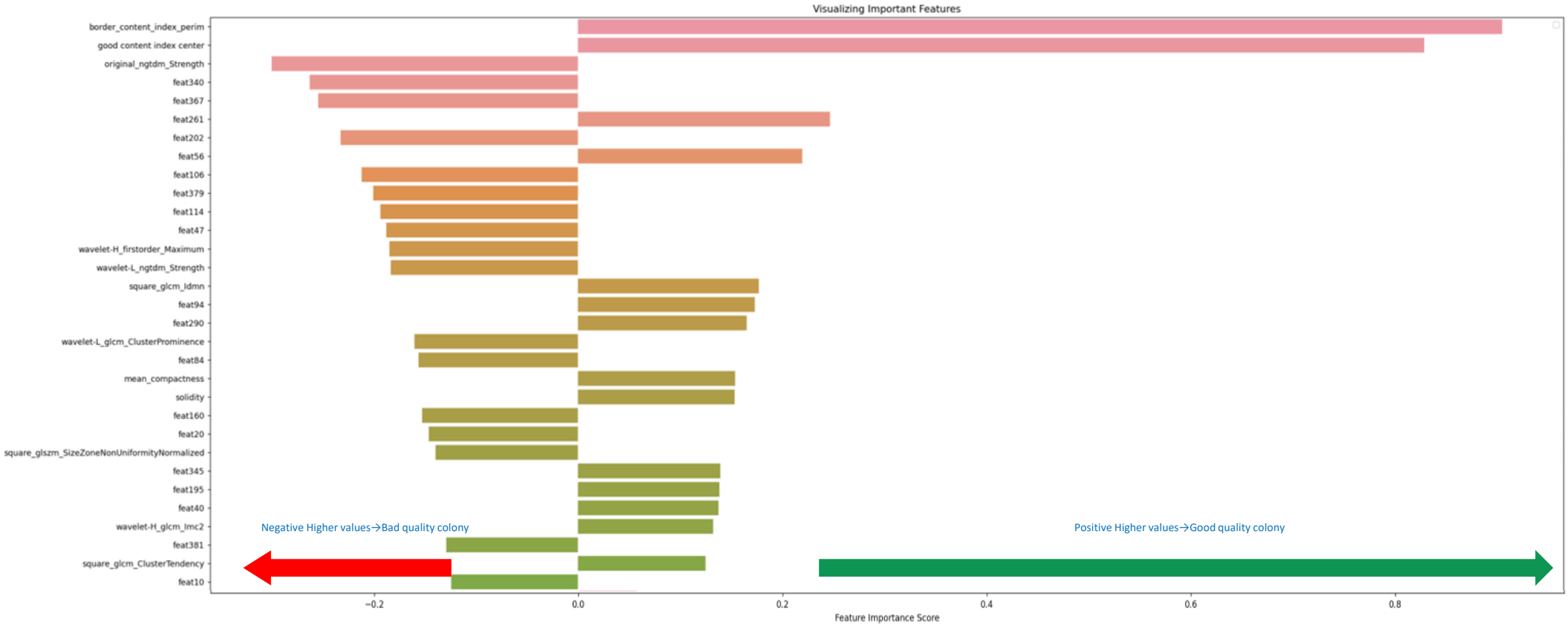
Detect and separate iPSC colonies

Quality Assessment



FEATURES IMPORTANCE



A negative weight indicates that higher values of this feature contribute to increasing the model's prediction towards the bad quality colony

A positive weight indicates that higher values of this feature contribute to increasing the model's prediction towards the good quality colony

MIDA BUSINESS MODEL – IPSC

- Instrument sales
  - Automated solution for iPSC line production in small scale units
  - Ai-driven QC solution for iPSCs and differentiated cells

- Strategic partnerships/collaboration
  - Development of complete production lines for iPSC derived cell products

- iPSC line generation (autologous/allogeneic)

- Sales of data associated to generation iPSC lines and associated differentiation

Customer segments:
Biotech/Pharma companies with developed therapies in need of production solutions
Biotech/pharma clients who need cGMP adaptation of early stage product candidates

MIDA Biotech

creating an innovation platform to develop
game changing stem cell therapies

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THANK YOU!