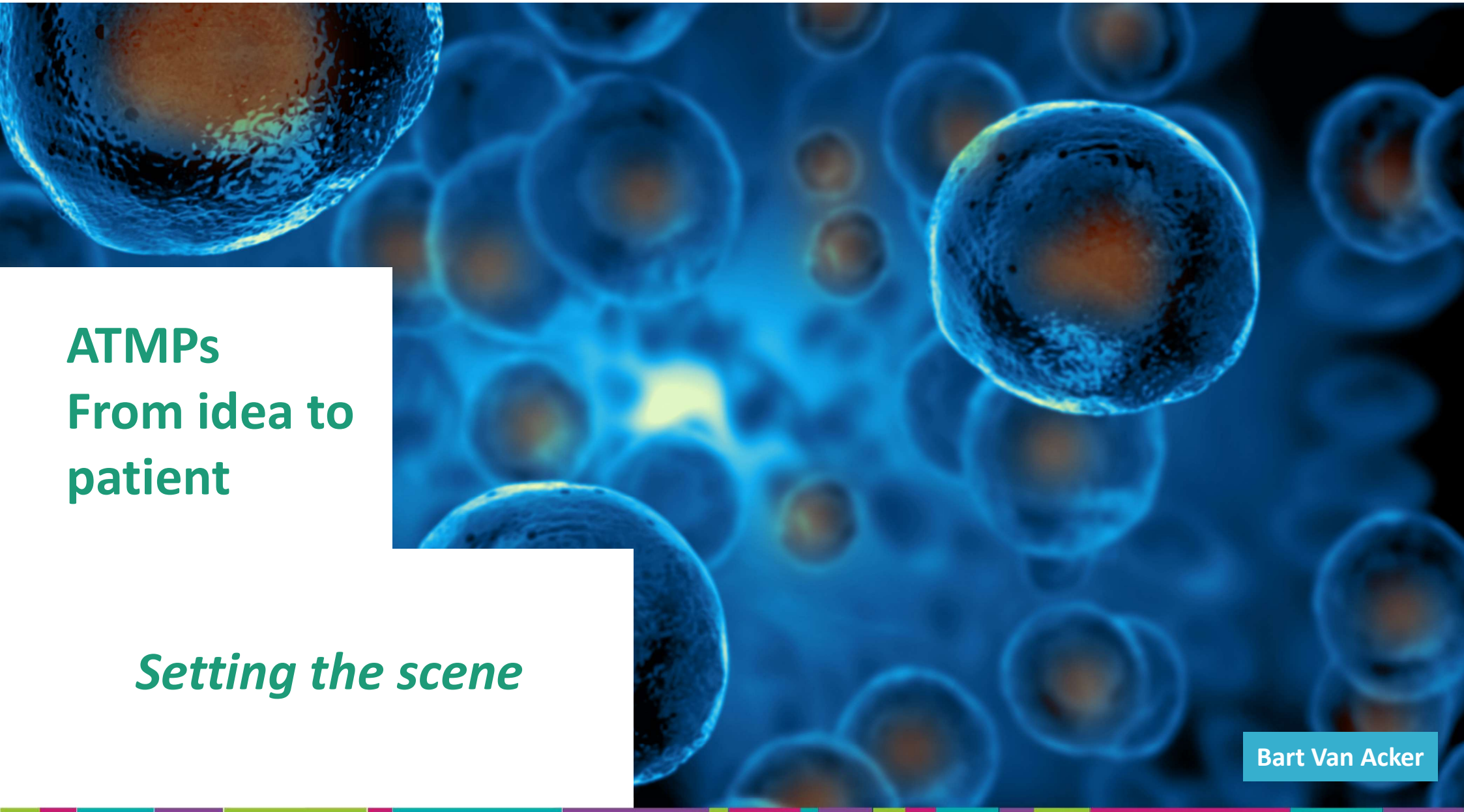


ATMPs
From idea to patient

Setting the scene

Bart Van Acker

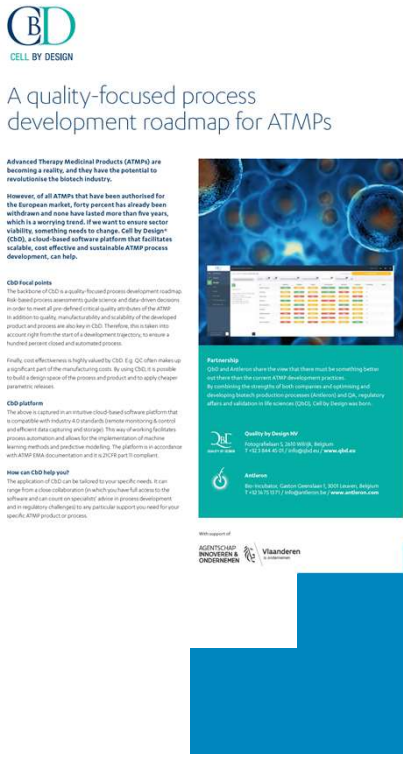
Introduction

- **Founder of the QBD and YEOTY 2019**
- **Consulting & Solution provider in QA, Validation, Regulatory & PM**
- **190 employees and offices in 7 countries**
- **Two focal points: ATMPs and Medical devices**
- **Solutions for ATMPs companies:**

1. Cell by Design
   Software platform & methodology for process development for ATMPs

2. ATMPKick
   MES for ATMPs (developed with neuroplast STEM CELL TECHNOLOGY)

3. QualityKick
   Cloud based and validated Quality Management system (SAAS)



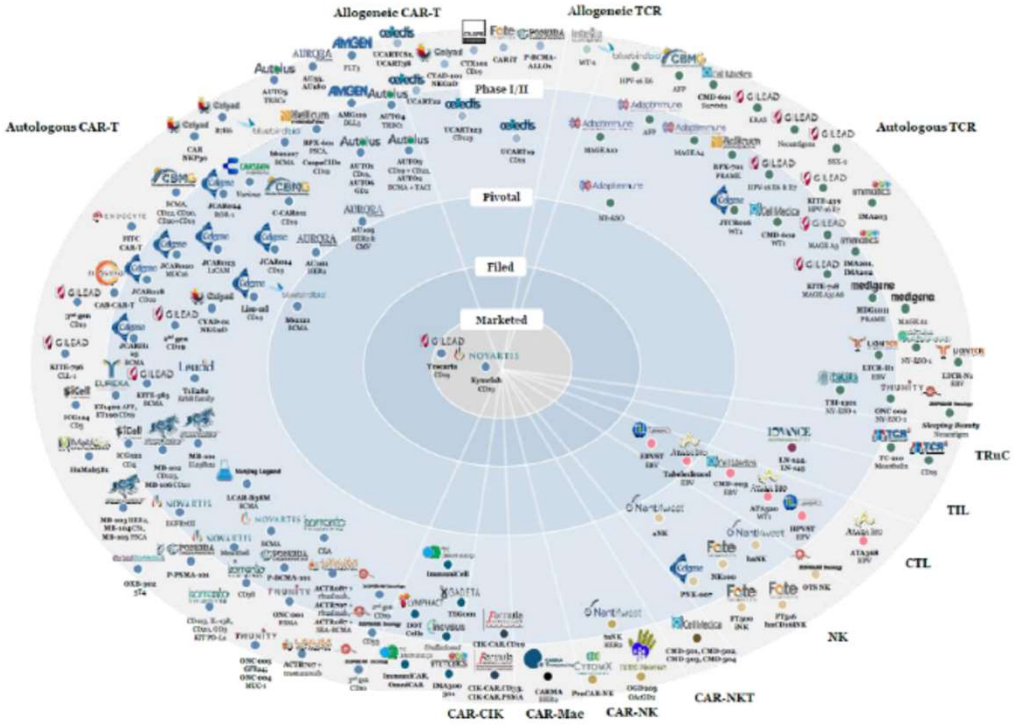
Antleron
Engineering life

neuroplast
STEM CELL TECHNOLOGY

INOVIGATE
achieving outcomes

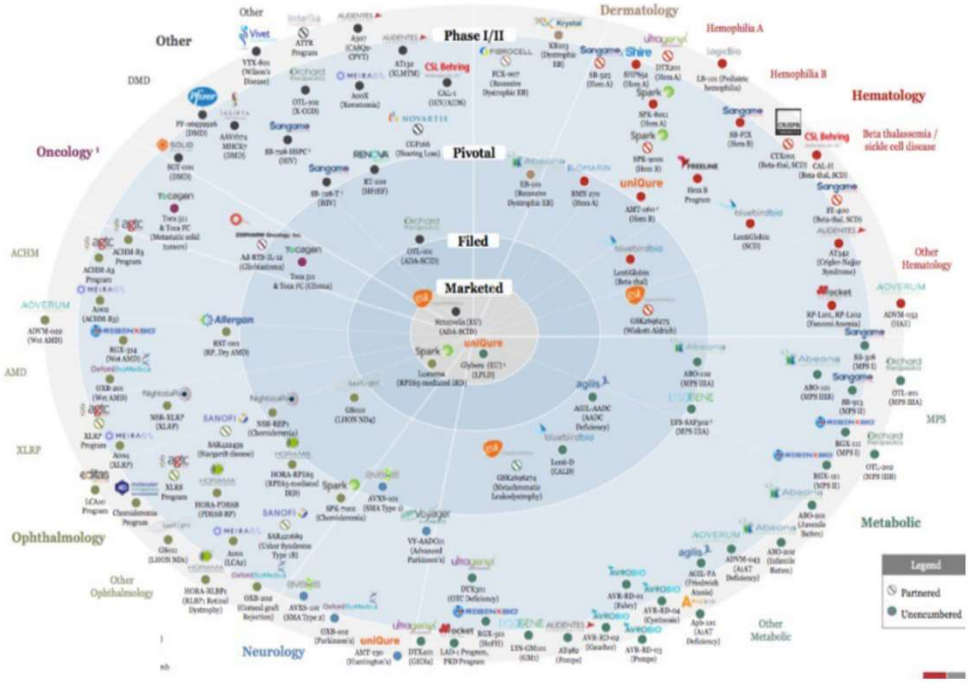
QBD
QUALITY BY DESIGN

Immune-oncology Landscape



Source: Wells Fargo Securities/Cryoport

Gene Therapy Landscape



Source: Wells Fargo Securities/Cryoport

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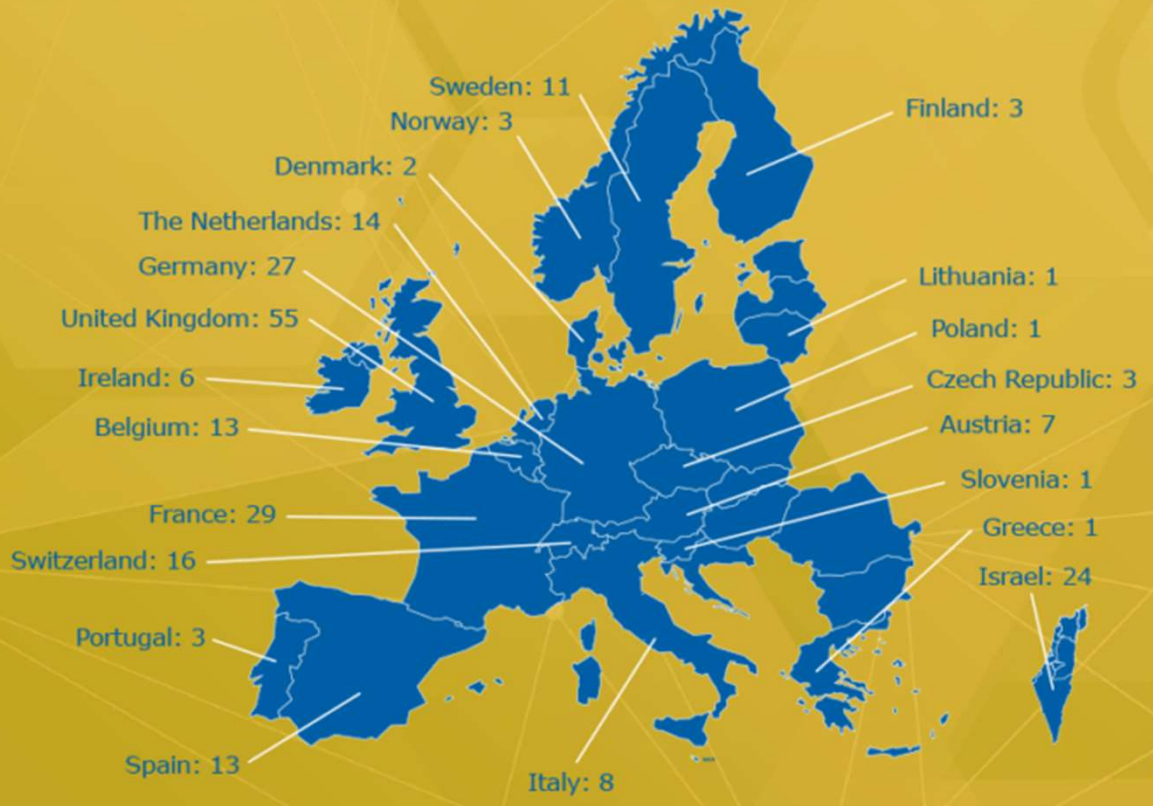
INOVIGATE
achieving outcomes

QBD
QUALITY BY DESIGN

European Sector Landscape

241+ Regenerative Medicine /Advanced Therapies Companies based in Europe/Israel



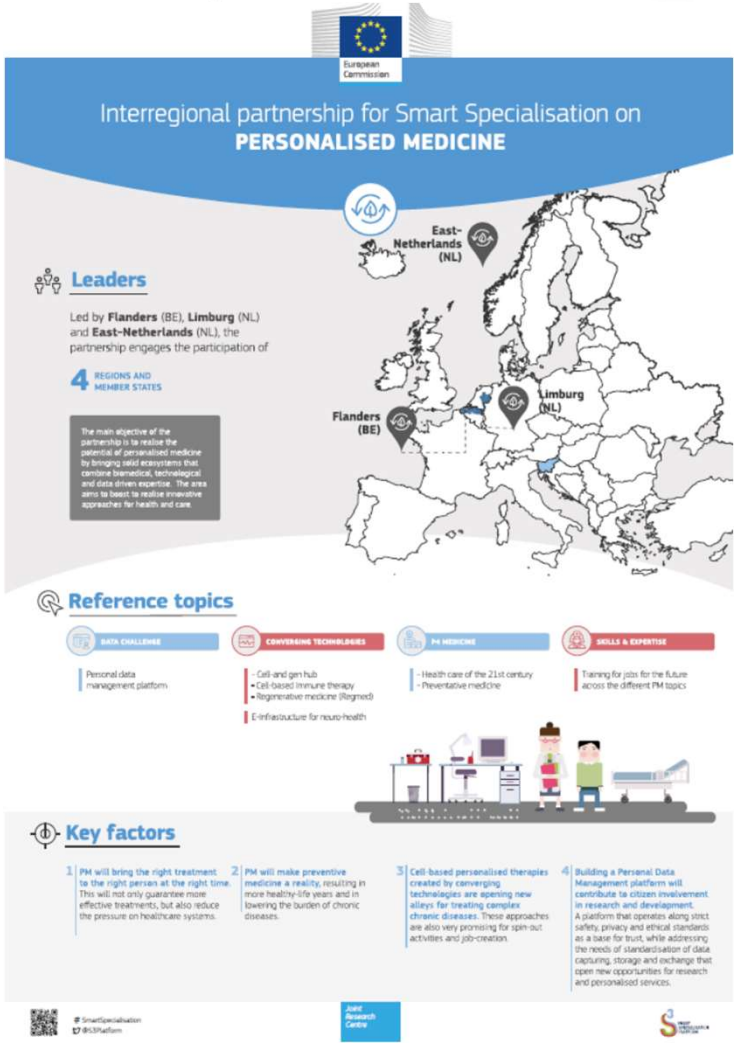
Alliance *for* Regenerative Medicine

Antleron Engineering life

neuroplast STEM CELL TECHNOLOGY

INOVIGATE achieving outcomes

QBD QUALITY BY DESIGN



30 TRIALS IN TOTAL
INCLUDING 19 MULTINATIONAL TRIALS

By product type:

Tissue-Engineered Product: 7 trials

Somatic Cell Therapy Product: 2 trials

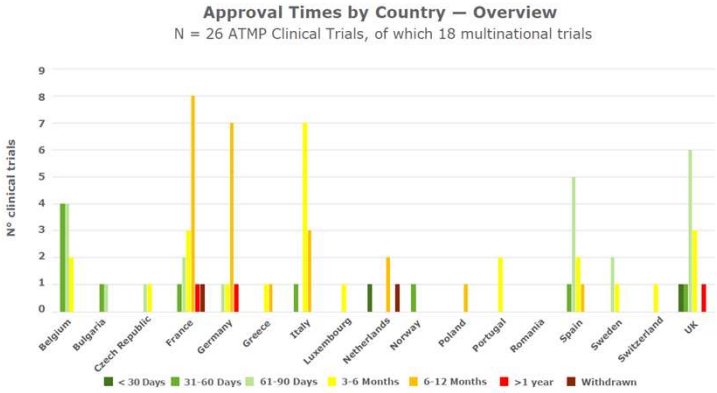
Gene Therapy Product: 16 trials

Chimeric Antigen Receptor T Cell Therapy: 5 trials

By phase:

Phase I : 3
Phase I/II: 9
Phase II : 9
Phase II/III : 1
Phase III : 8

› According to respondents, the most important criterion for selecting a clinical trial site and a country is the expertise and the skills of the clinical centers and healthcare professionals, followed by the speed of approval by regulatory authorities, and the quality of the review or expertise of the regulatory authorities.



https://s3platform.jrc.ec.europa.eu/personalised-medicine

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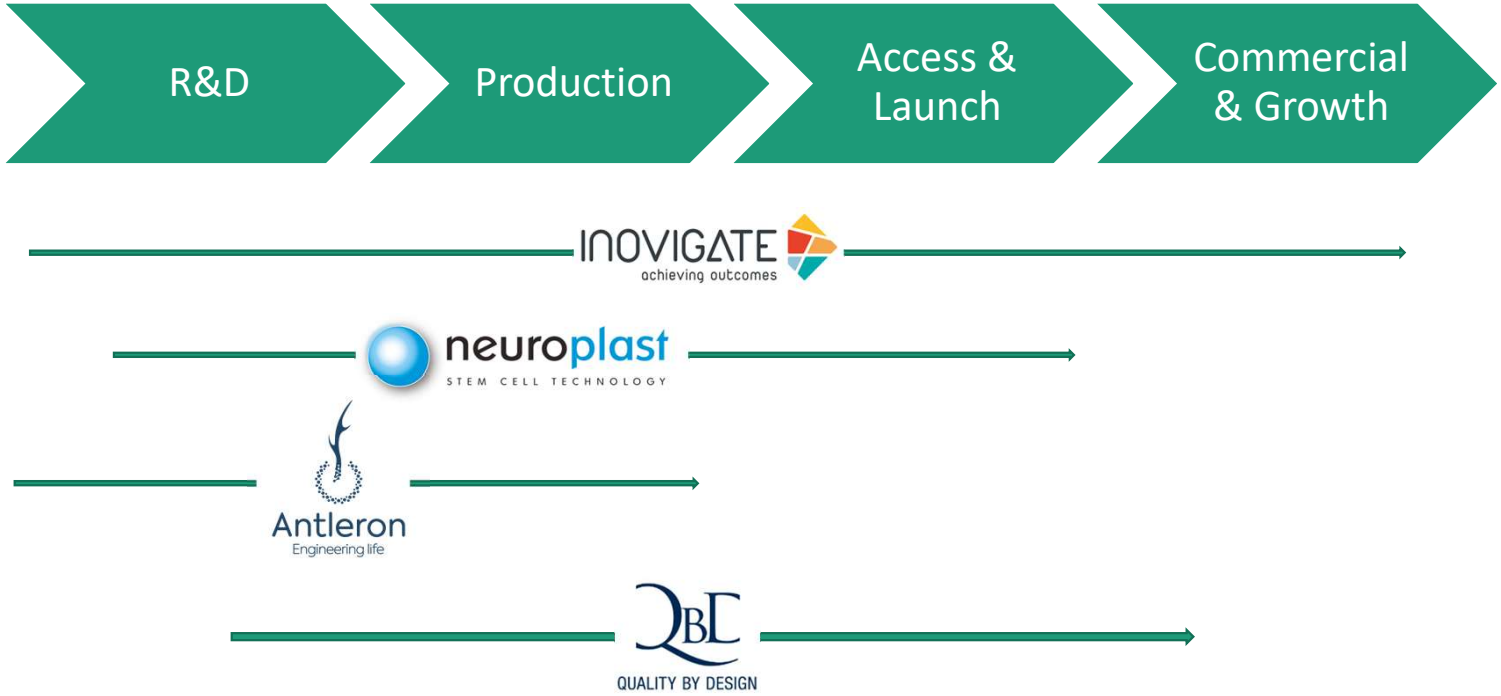
neuroplast STEM CELL TECHNOLOGY

INOVIGATE achieving outcomes

QBE QUALITY BY DESIGN

ATMP Challenges

End to end approach



We wish you a very informative morning session!