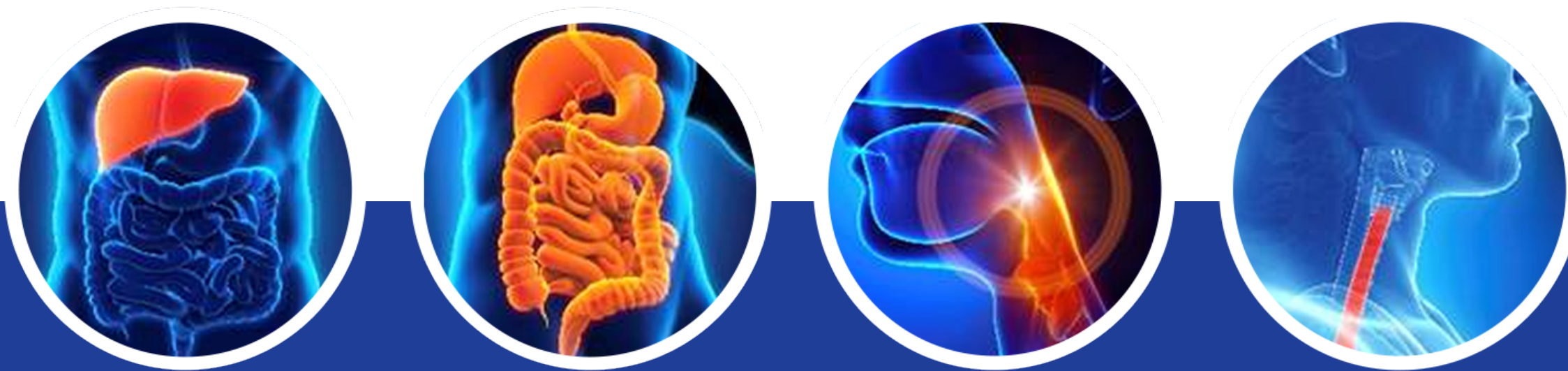


videregen

REGENERATION REINVENTED



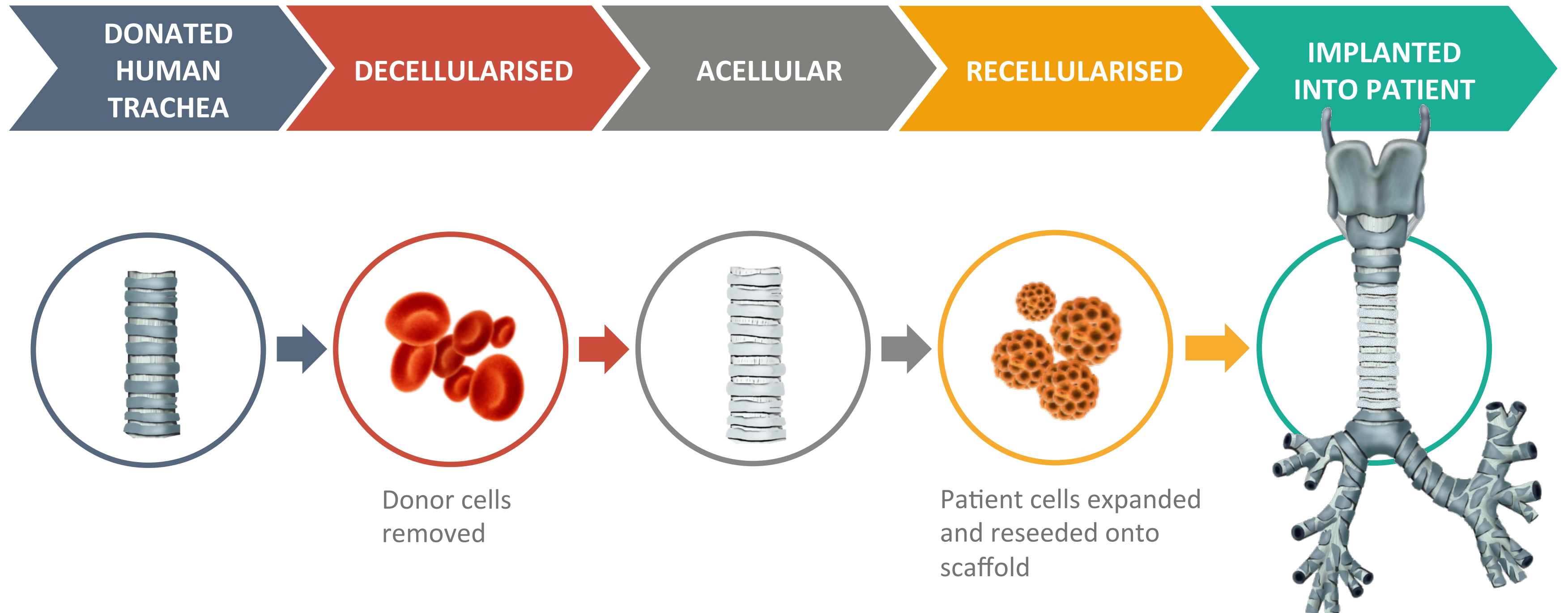
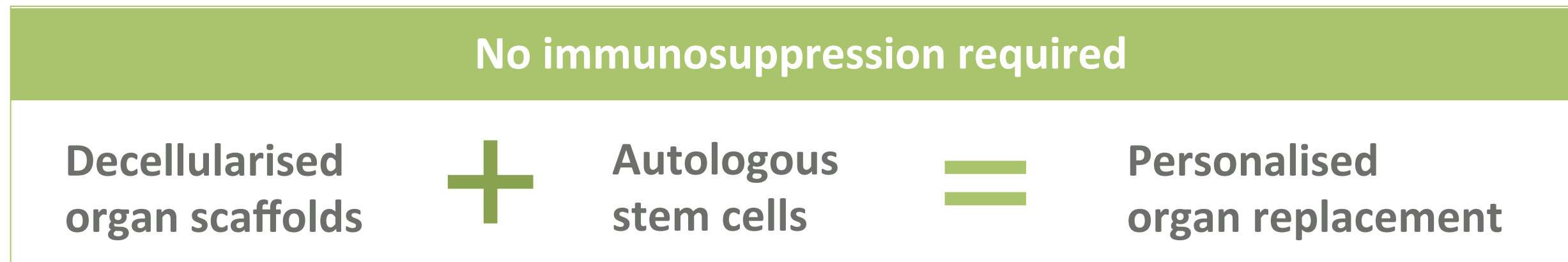
Emerging Medicinal Products – from laboratory to patient use

14th December 2015

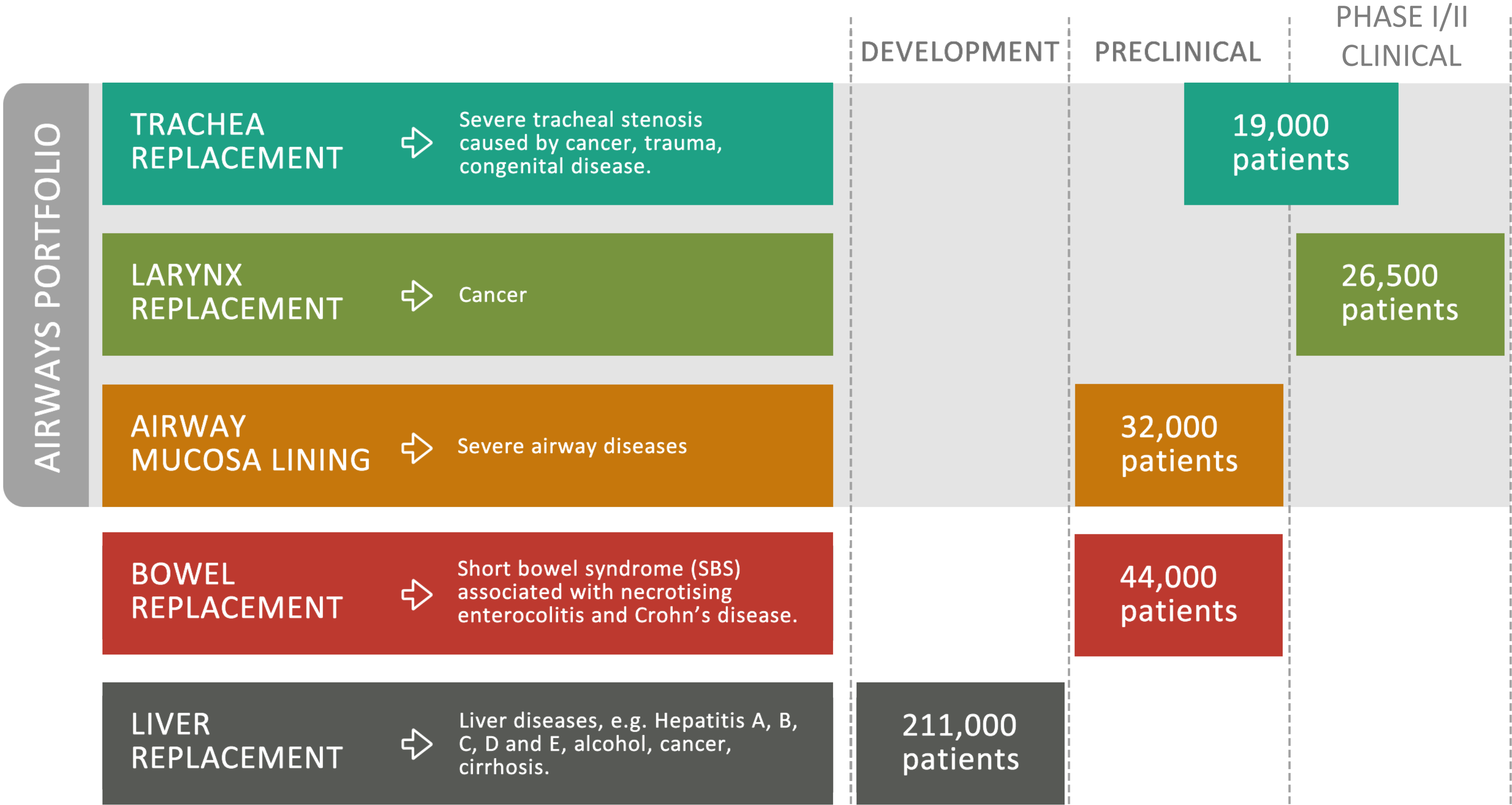
Dr Steve Bloor, CEO

Personalised, non-immunogenic organ replacement products
for orphan indications

TISSUE ENGINEERED PRODUCT - CORE TECHNOLOGY



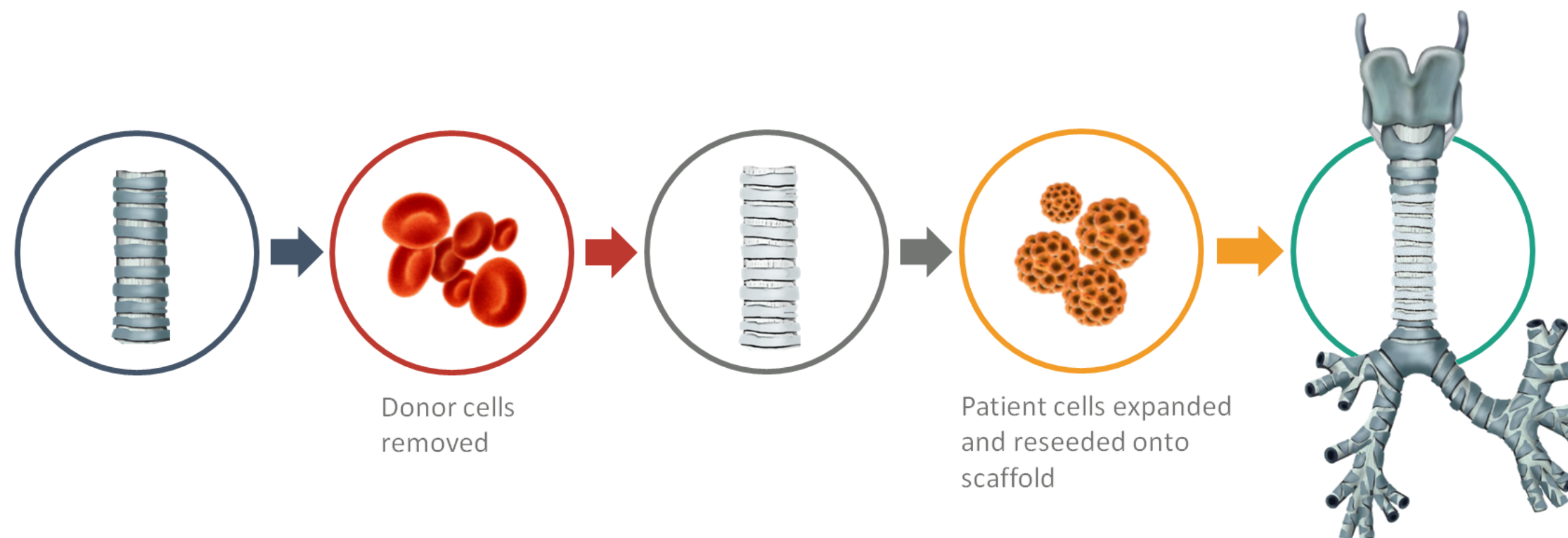
PRODUCT PORTFOLIO AND TARGET PATIENT POPULATION



TISSUE ENGINEERED TRACHEA - ATMP PRODUCT

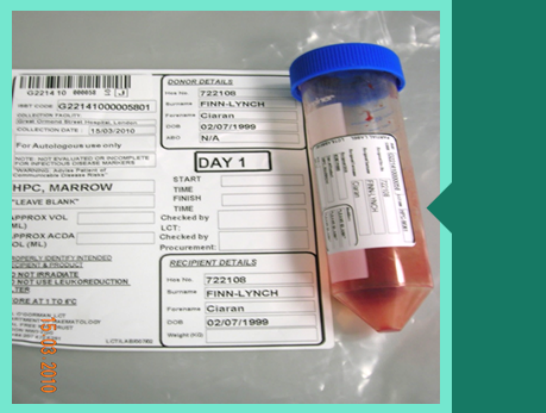
The product is a human-derived mesenchymal stromal cells (MSCs)-seeded trachea which comprises two components:

- Starting material comprising a human allogeneic decellularised tracheal scaffold from a cadaveric donor (Tissue Product)
- Autologous bone marrow (BM)-derived MSCs (Drug Substance)

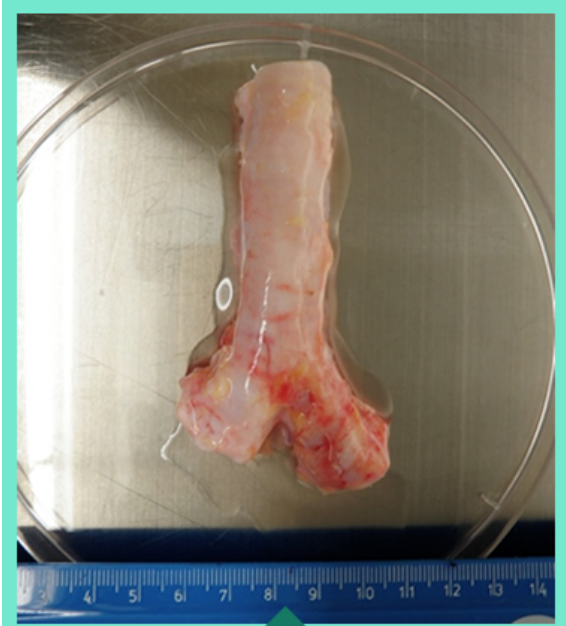
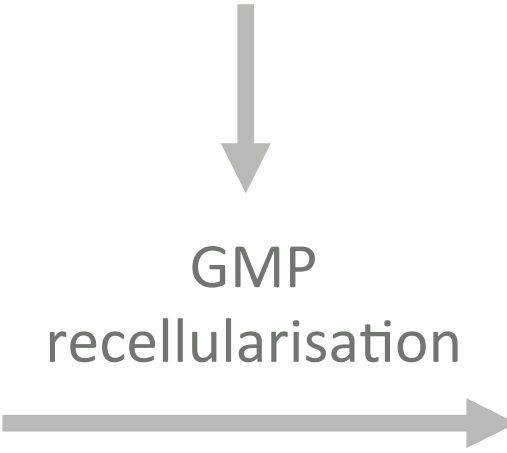


GMP MANUFACTURING PROCESS FLOW

Bone marrow aspirate



Autologous MSC harvesting, isolation and expansion



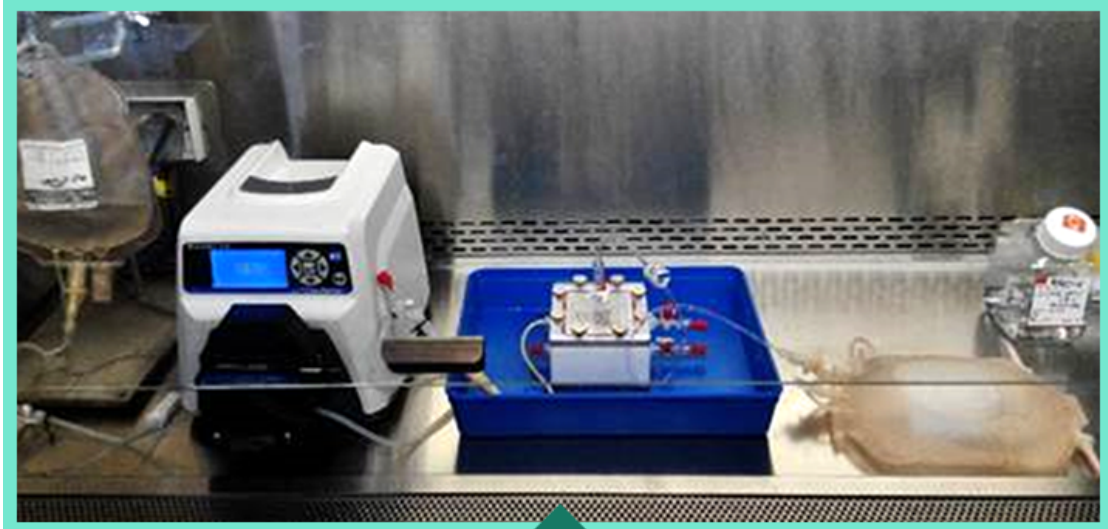
Organ harvesting

GMP decellularisation

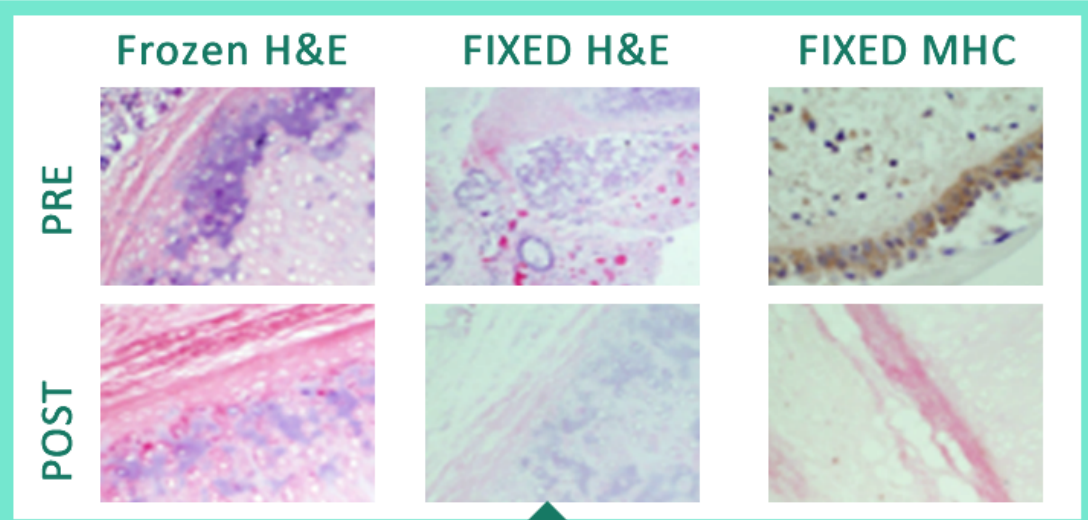


Decellularised trachea

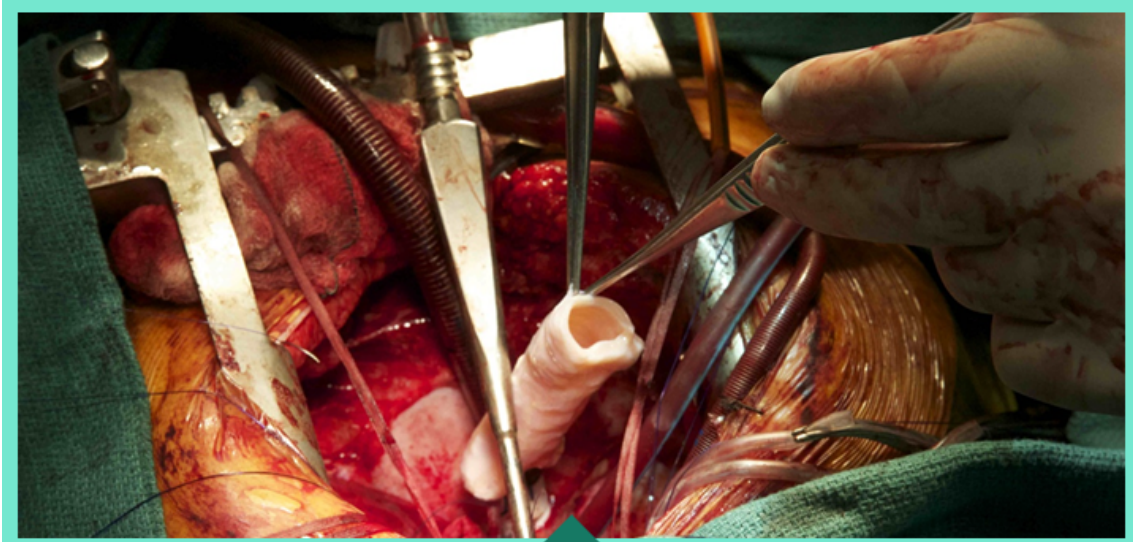
GMP recellularisation



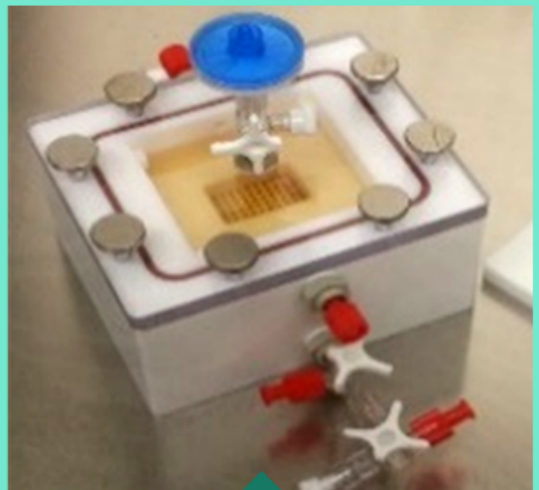
MSC recellularisation



GMP QC and product release



Transplantation



Transportation



CHALLENGES – From First-In-Man To Market

Non-Clinical & Clinical

- Appropriate models of safety and performance that translate to human experience
- Orphan indication – low numbers
- Statistical power of defined endpoints
- No formal control group – use of historical data
- Approval route and when to define/commit

Chemistry, Manufacturing and Controls

- Biologic tissue scaffold – natural variability – difficult to correlate chemical, biological and physical characteristics to clinical performance
- Autologous MSC's
 - Donor/patient variability – effects of age on cell characteristics
 - Identity, purity, viability, genetic stability, potency (correlation to clinical performance?)
- Final product testing & release
 - Short shelf-life limits pre-release testing
 - 1 trachea/organ = 1 batch – limits sampling/testing
 - Challenge to correlate quality/test data to clinical performance or risk
 - Product quality evolves over time from release to patient

Reimbursement

- Engagement with HTA's, reimbursement model and data set required



Leaders in the development
of autologous tissue engineered products

FOR FURTHER INFORMATION PLEASE CONTACT



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