



Webinar Highlights

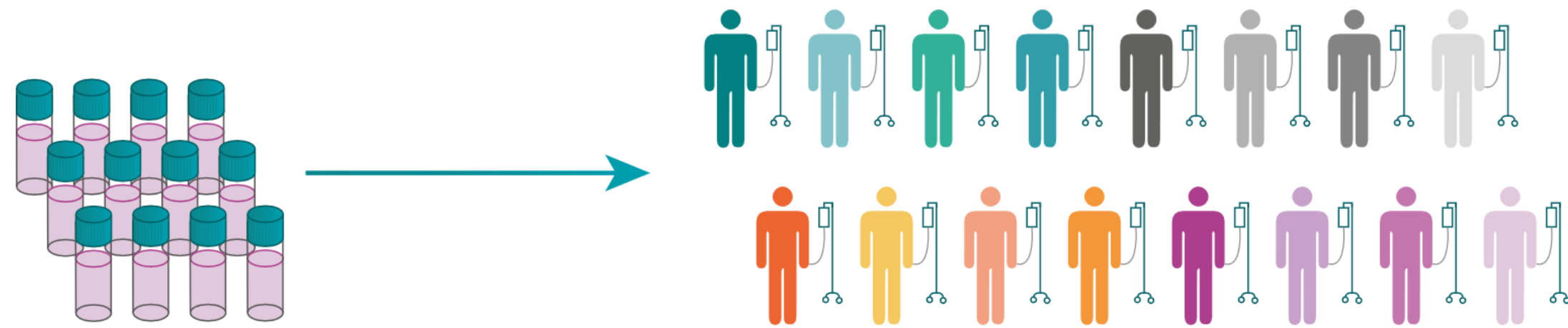
# Transforming Personalized Medicine into Off-the-Shelf Cell Therapies

Discover novel data-driven solutions to tackle the scalability and accessibility challenges associated with advanced therapeutic medicinal products.

# How cell therapies differ from 'traditional' pharmaceuticals

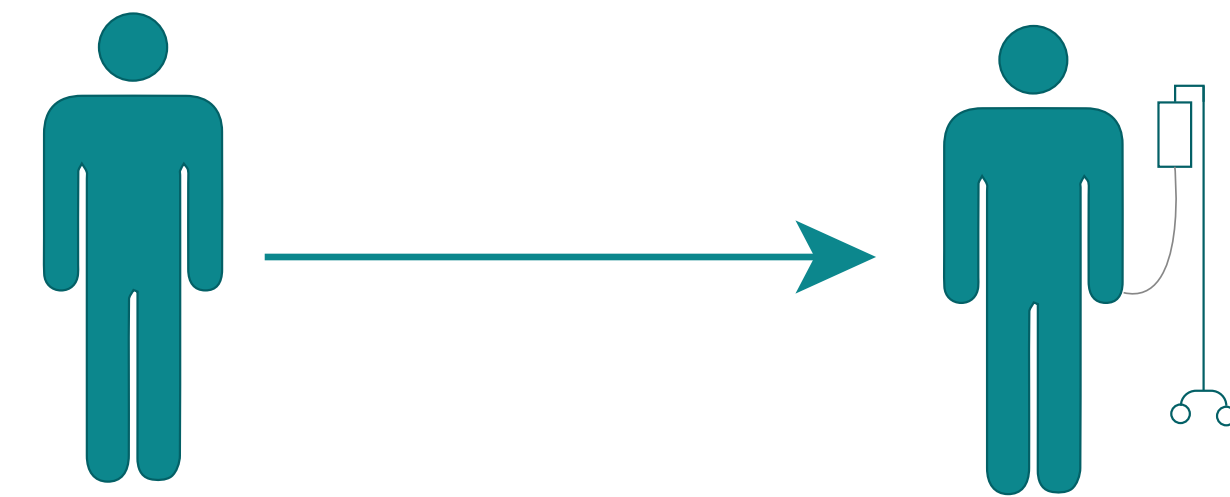


- Chemical pharmaceutical: e.g. Small Molecule
  - Controlled and fully characterised starting material and manufacturing process
- Biologicals
  - Manufactured in biological systems



**One batch thousand of doses**

- Cell therapy products (currently marketed products)
  - Starting material: high variability from donor to donor
  - Ad hoc manufacturing process: high variability, high cost



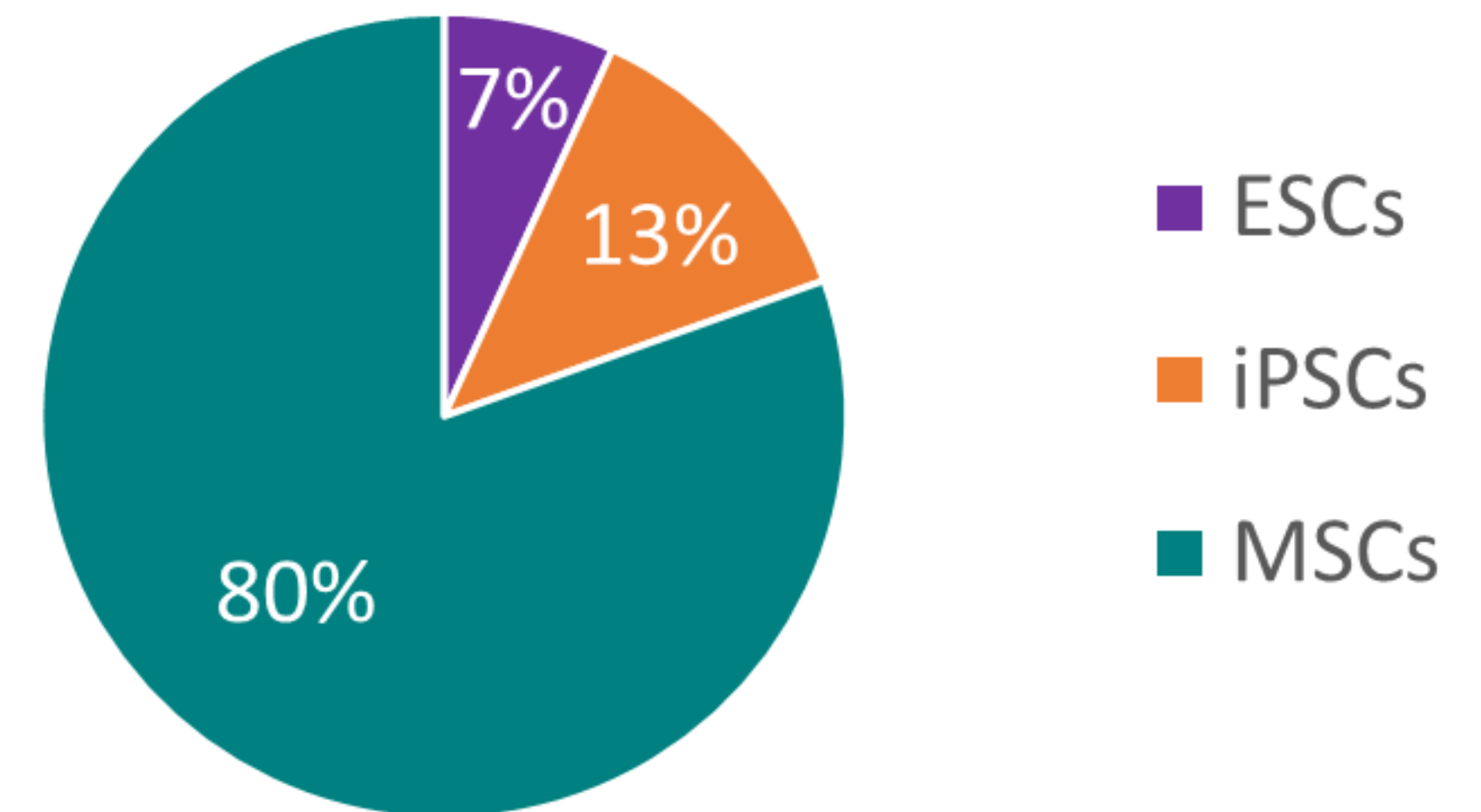
**One batch one dose**

# Starting material: possible sources



- Human Embryonic Stem Cells (hESCs)
  - Ethical issues in sourcing
- Induced Pluripotent Stem Cells (iPSCs)
  - Safety issues: undesired differentiation and malignant transformation
- Mesenchymal Stem Cells (MSCs)
  - Successful applications in autoimmune and chronic inflammatory diseases
  - Safety issues: can promote tumor growth and metastasis

Clinical Trials: Use of ESCs, iPSCs and MSCs in Medicine



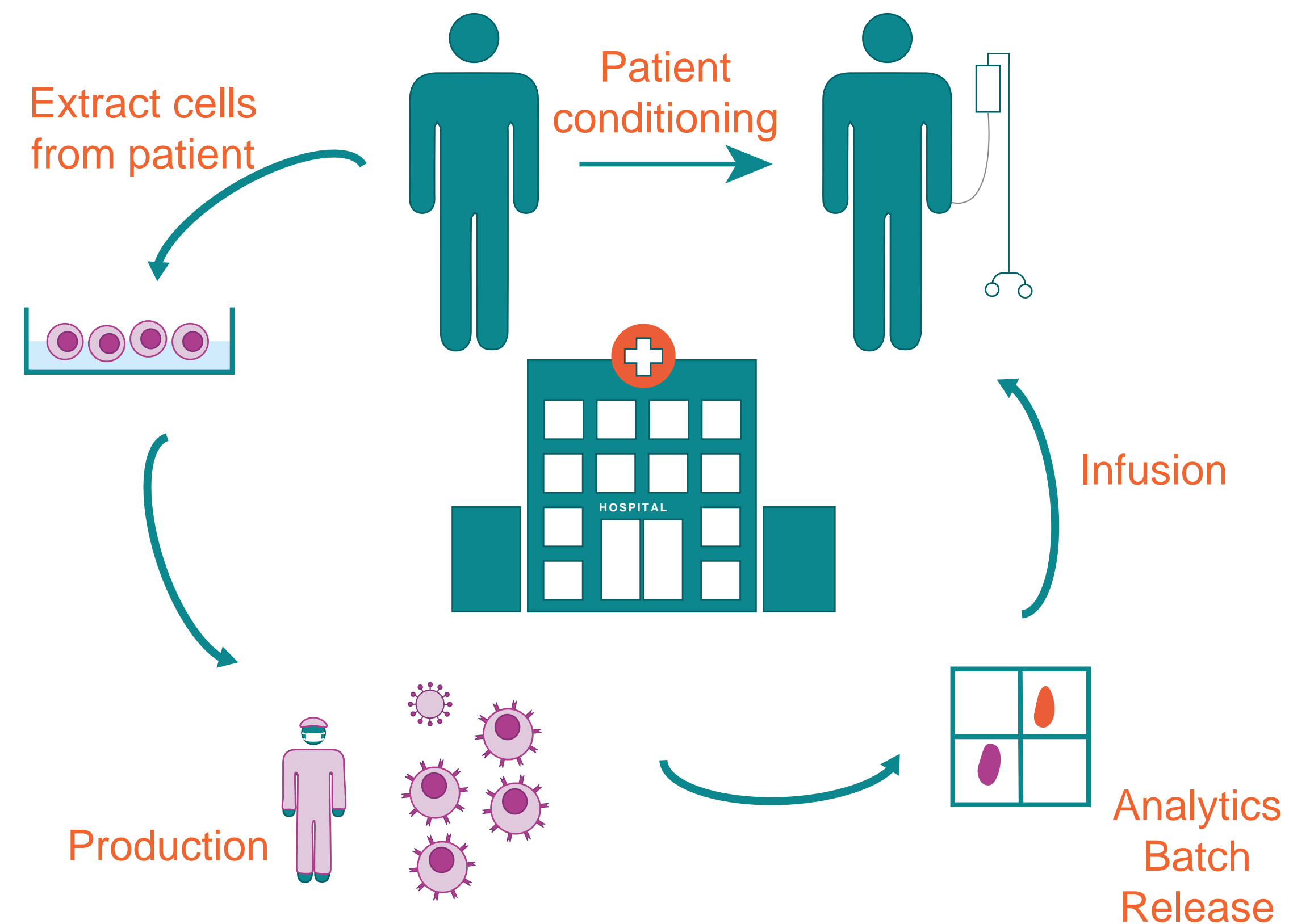
*Data was obtained from 'clinicaltrial.gov' on May 28, 2020. Filters applied for the search: condition or disease: none; other terms: ESCs or iPSCs or MSCs; country: no entry; status: recruiting, enrolling by invitation and active, not recruiting.*

# Autologous cell therapy: a personalized treatment



## ■ Scale-out model:

- Born in academic/clinical settings
- Autologous therapy:
  - Variability of starting material: quality and quantity
  - Vein-to-vein cycle, 2 weeks
  - Integration of clinical-manufacturing-analytical teams
- Manufacturing and analytics:
  - At hospital site or nearby
  - Limited output capacity, manual or semi-automated process
  - Chain of custody, chain of identity
  - Vulnerable supply chain: Small volume of orders, storage capacity



## ■ High cost

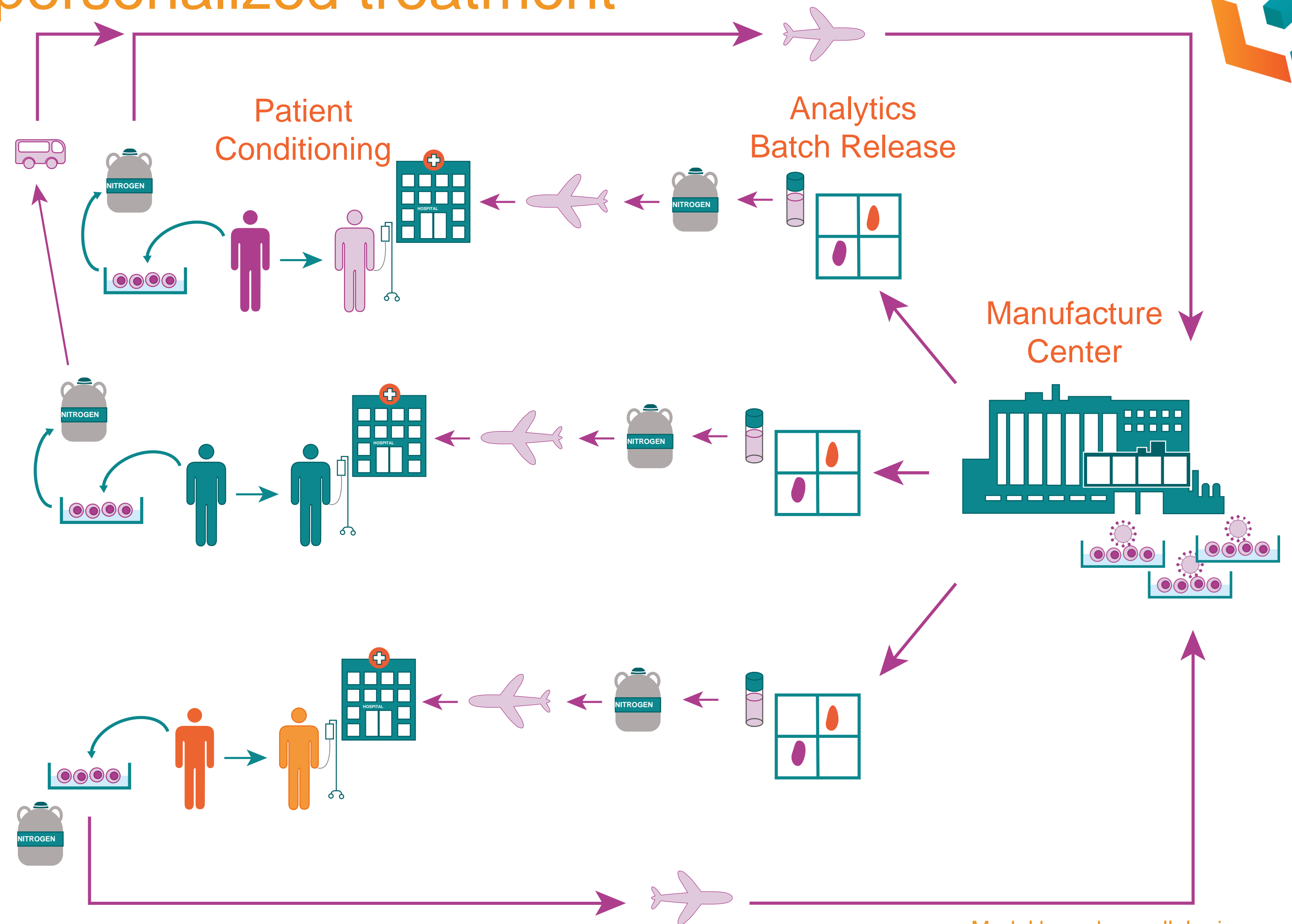
# Autologous cell therapy: a personalized treatment



## Hybrid model:

- Autologous therapy: same challenges as in the scale-out model
- Manufacturing and analytics:
  - Centralized at manufacturing center
  - High output capacity, automated
  - Challenging transportation
  - Chain of custody, chain of identity
- Strong supply chain
  - Large volume of orders
  - Large storage capacity

## High cost



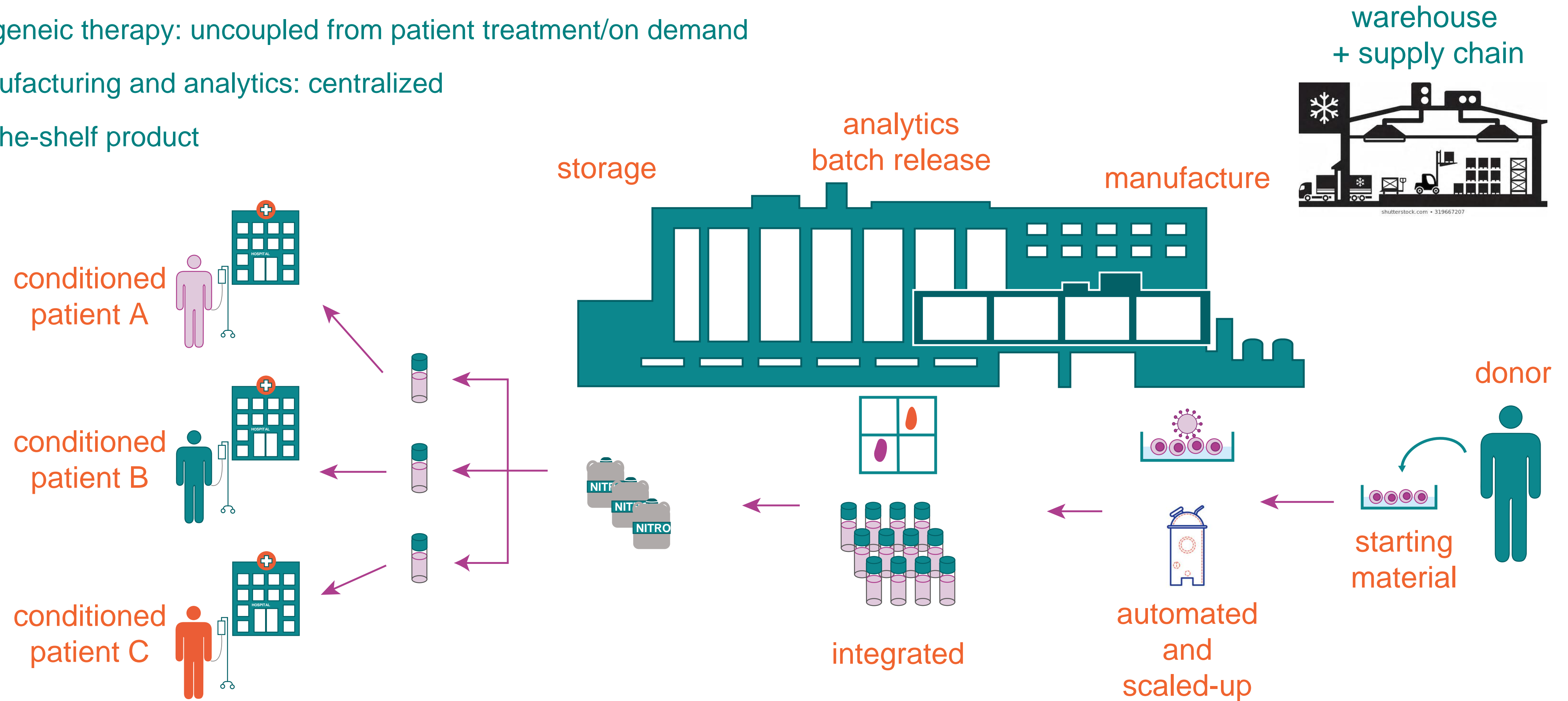
Model based on cellular immunotherapy

# Allogeneic cell therapy: an 'off-the shelf' treatment



## Scale-up model:

- Allogeneic therapy: uncoupled from patient treatment/on demand
- Manufacturing and analytics: centralized
- Off-the-shelf product



# Summary



Cell therapy provides new alternatives for oncology, but further development is needed to improve efficacy, safety and scalability.



## Current approved therapies are autologous, one batch for one patient

- Scale-out model:
  - Patient to patient **variability**
  - Fragmentation and repetition of activities, **increased vulnerability**
  - **High cost**

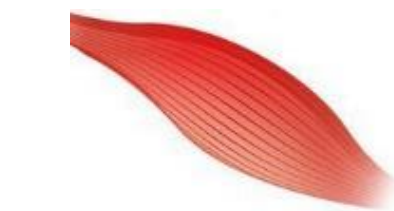
## 'Off-the-shelf' allogenic therapy, one batch for many patients

- Scale-up model:
  - **High throughput/productivity**: starting material available in larger quantity and fully characterised
  - Improved **availability**: products available in storage
  - **Centralized** production
  - **Cost reduction/more accessibility to patients**

# Mogrify technology: a universal cell conversion technology



Fibroblasts



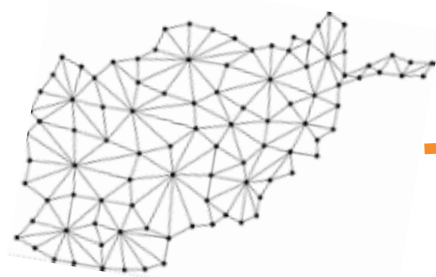
Keratinocyte



iPSC



Unhealthy / Old



Cell State A

Systematic identification of master cell switch



Cardiomyocytes



Neurons



Intestinal



Healthy / Young



Cell State B





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