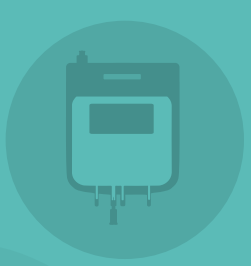
RegMedNet | In focus

Catalent CELL & GENE THERAPY

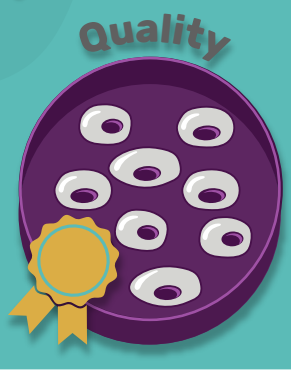
Features of iPSCs as starting materials that can transform cell therapies into standard care

Safe and ethical
– by source and design

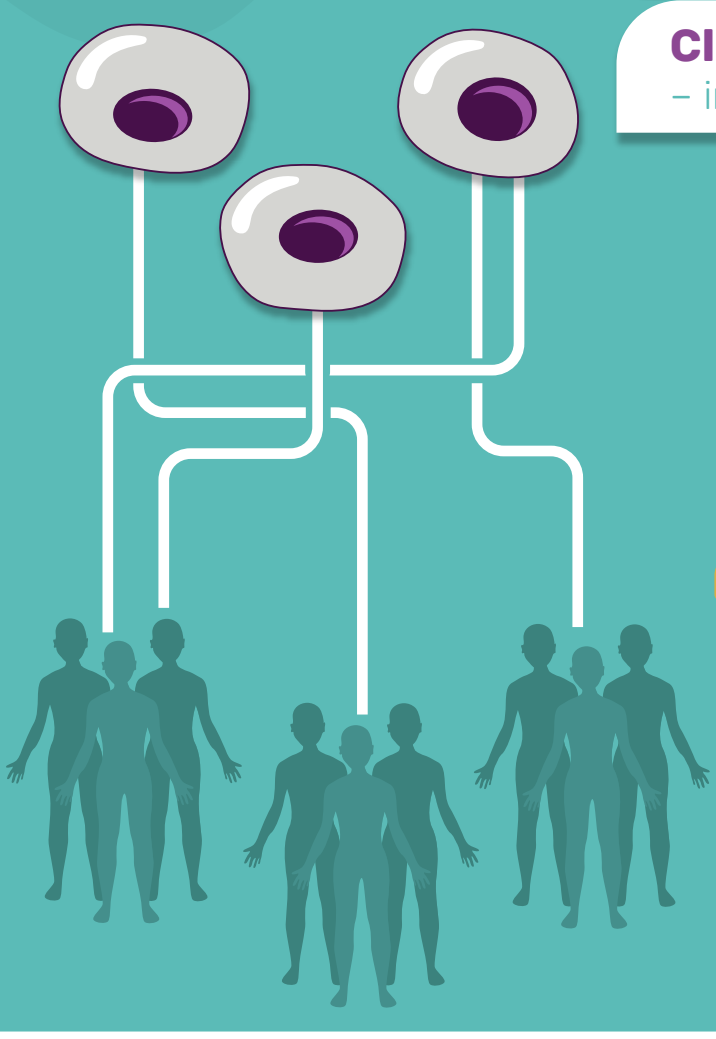
1 Pre-consented for commercial therapeutic use:
the donor of the cells must have consented to the use of their biological material for commercial therapeutic use. For this reason and their low mutation load, cells from cord blood are a particularly good source that is also free of ethical concerns.



2 Clinically collected source:
the environment and procedure under which cells are collected to be used later in pluripotency induction is a critical aspect. Is documentation of the donor and process adequate? Is processing of collected materials standardized and aligned with clinical guidelines?



3 Genomically and functionally intact (critical quality attributes):
at a minimum, iPSCs destined for therapies must meet critical quality attributes outlined in authoritative publications. The genetic integrity of both the sourced material and the resulting iPSCs should also be confirmed by whole-genome analysis.



Clinically relevant
– in use and access

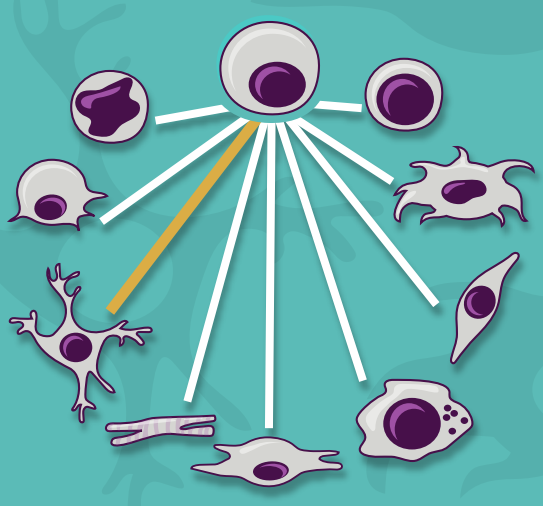
1 Flexible to personalize:
a starting material that can be adapted to meet requirements of a broad range of therapies is attractive because increased experience with the starting material makes it easier to use in the next therapy.

2 Matched to a broader cohort (immune compatibility):
having a starting material that is already from the get-go a better match for a broader fraction of the population is a better starting point for any therapy. Such allogeneic approaches include HLA-homozygous cell lines.

3 Shorter and safer path to patients:
starting materials that eliminate logistical hurdles will make cell therapies available to a broader population because of cost savings, time savings and less reliance on proximity to the infrastructure behind their logistics.

Commercial catalyst
– a universal, consistent starting point

1 Immediacy of use and longevity of availability:
consider a cellular starting material that is ready to use – that is, where you don't have to develop it yourself – and is inexhaustibly available.



2 Uncompromised quality and consistent attributes:
with a starting material that is inexhaustible, no matter at what point you are in your development, you can count on having a batch-to-batch consistent starting material every time you order.

3 Continuity from development to preclinical to clinical:
to a developer at the beginning of a pipeline, the cost of a starting material must match the potential outcomes — they won't want to invest in high-grade, GMP starting materials at that point. Starting materials should be available as identical materials but in research- and GMP-grade.

4 Springboard for commercial innovation:
a cellular starting material that can be differentiated into almost any cell type, that can be edited towards personalization, that is highly standardized in its production, and that is consistent from one batch to the next, is a starting material that serves as a blank slate for innovation.

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This infographic was created as part of the RegMedNet In focus on cellular starting materials for cell therapies in association with RheinCell Therapeutics.