

Maximize Starting Material Consistency

Plan an efficient characterization strategy for allogeneic cell therapy starting material



Diverse Donor Pool

At early stage, use starting material from a wider donor pool

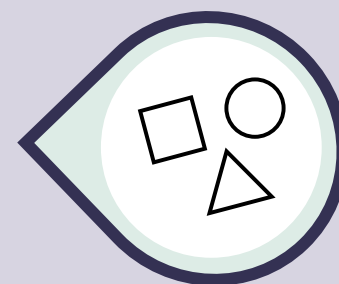
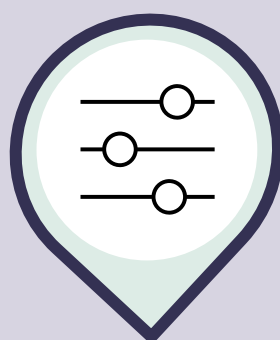
START

Early Characterization

Basic characterization using combination of phenotyping, cell quality, cell numbers

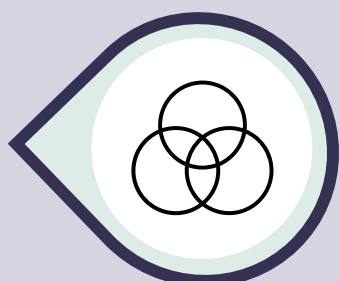
Optimize Conditions

Use early characterization data to optimize collection method, shelf life, preservation conditions to ensure starting material quality and purity



Advanced Characterization

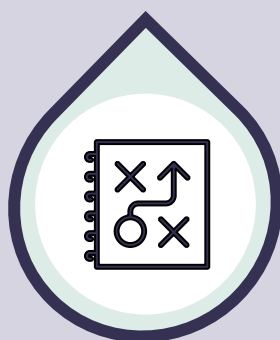
Associate deeper phenotypic, genomic, proteomic, and functional characteristics to clinical outcome



Strategic Variability Control

Set donor selection criteria (e.g., demographics, threshold on cell composition, expression of genetic or protein marker)

Implement process steps (e.g., depletion, isolation, genetic modification, culture conditions)



Life cycle

Balance appropriate characterization and release assays to ensure product consistency and CQA are achieved

FINISH