# 2ND INTERNATIONAL CONFERENCE ON CELL SCIENCE AND REGENERATIVE MEDICINE

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## Transcriptomic Platform for Donor Characterization in Cell Therapies

**Abstract:** Cell therapies use living cells to repair or treat damaged tissues, with the cells' origin playing a crucial role in the effectiveness of the treatment. The manufacturing process follows common steps shared across cell therapy production, typically including the generation of a master stock, a drug substance, and ultimately the final drug product.

We have developed an in-house transcriptomic platform with three main goals: (1) to build a library of all batches used in clinical and commertial , (2) to identify transcriptomic signatures associated with favorable efficacy outcomes in order to guide the selection of intermediate products for expansion into the final product, and (3) to study transcriptomic changes throughout the manufacturing process. Variability in batch performance suggests that higher remission rates may be linked to specific characteristics of the source material or specific cell types or subpopulations.

To address these aims, we have conducted transcriptomic analyses in different scenarios: baseline projects, where we assess batch differences; stimulation projects, designed to replicate in vitro the inflammatory conditions where the therapy will act and evaluate batch-specific responses; and longitudinal projects, which track cellular changes across manufacturing stages.

Single-cell RNA sequencing is performed using 10x Genomics and Illumina platforms. Count matrices are generated with the Cell Ranger pipeline. Downstream analyses focus on identifying cell subpopulations, characterizing their functions, evaluating changes under stimulation, and finding differentially expressed genes and pathways.

Striking observations have been identified using this platform, for example, the impact of geographical origin on transcriptomic profiles, the effect of inflammatory stimuli in mimicking patient conditions, and the homogenizing effect of the manufacturing process, with MCS samples showing greater diversity than their corresponding DS products.

**Keywords:** Cell therapy, transcriptomics, bioinformatics, single-cell RNA-seq, batch variability, inflammatory stimulation