There is no "one size fits all" approach for CGT products given the broad diversity of modalities and corresponding properties.

Developing CGTP for ultra/rare diseases has many challenges. The cost of manufacturing AAV GT is extremely high. There is a call for CMC expertise to drive down the cost of production.

Cellular starting materials (CSM) need to be characterized and, to the extent possible, their variability understood and taken into account when the sponsor sets specifications and conducts comparability assessments. We are beginning to see developers undertake the complex task of characterizing CSM.