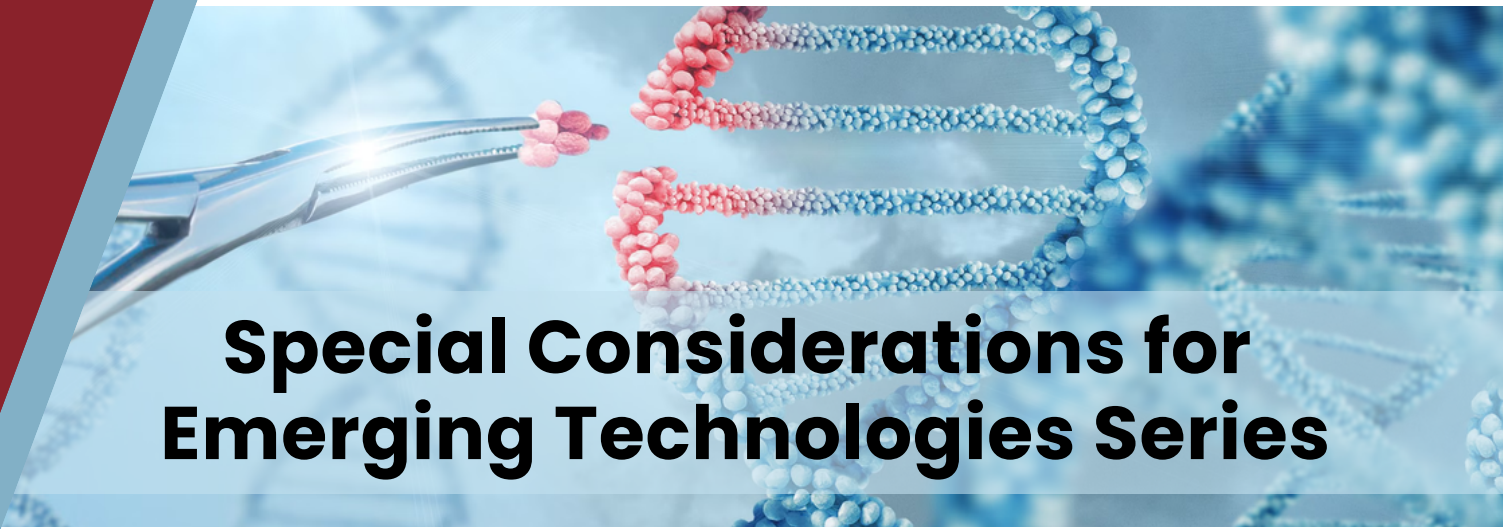




Special Considerations for Emerging Technologies Series

Module 1: Cell and Gene Therapy Trials

DESCRIPTION

The USC Mann D.K. Kim International Center for Regulatory Science and the Regulatory Knowledge and Support (RKS) core within the Southern California Clinical and Translational Science Institute (SC CTSI) previously developed a self-study Clinical Trial Quality Training series to strengthen investigator-initiated trials through training in clinical site monitoring, auditing, and inspection readiness. Building on this foundation, the Special Considerations for Emerging Technologies series was developed to address the unique requirements of cutting-edge therapies.

The first module in this learning series, Cell and Gene Therapy Trials, was developed in collaboration with the USC + CHLA Alpha Clinic. It is designed to promote high-quality practices in cell and gene therapy (CGT) research. This course features four chapters that introduce fundamental concepts in CGTs, examines opportunities and challenges inherent to CGT clinical trials, and provide practical case studies along with actionable resources such as templates and checklists.

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