Context: Investigator Initiated Trials for Regulatory Approval of New Indications

Trials in rare diseases can be particularly challenging.

Often investigators in specialized centers are especially interested in pursuing these indications for their patients via Investigator Initiated Trials.

However, these centers often struggle to meet level of collection and data cleaning as trials sponsored by companies.

Questions

1. **How flexible are regulators with respect to data quality issues from IITs like sparser data collection and less intensive medical review of data?**

1. **Are regulators willing to accept single arm trials conducted by investigators with supplemental data from sponsors (eg., from already approved indications)?**