SESSION IV: HOW TIGHTLY SHOULD INVESTIGATORS ATTEMPT TO CONTROL OR RESTRICT TREATMENT QUALITY IN A PRAGMATIC OR REAL-WORLD TRIAL?
On One Hand: Tight Control Needed to Support Valid Inference and Patient Safety
On The Other Hand: Loose Control Needed to Support Valid Inference and Patient Safety
Assumptions:

- Study question clearly defined (decision and decision-maker the study should inform)
- Data are of adequate quality to assess eligibility, key prognostic factors, treatment exposure, and outcomes.
- Treatments are assigned randomly or by some other method that supports valid inference.

In scope:

- Treatment, setting, provider control
- Participant safety
Decision Aid for Discussion

- How much would the effectiveness or safety of the study treatment(s) vary among providers or care settings? How is this variability related to different levels of resources, experience, or expertise?
- What level(s) of resources/experience/expertise are now present in the care settings in which results of this trial will be applied?
- What level(s) of resources/experience/expertise are now present in the care settings in which this trial could be conducted?
- What special vulnerabilities or risks are anticipated in the study population?
- Is there some minimal or floor level of treatment quality necessary for valid inference regarding the study question?
- Is there some minimal or floor level of treatment quality necessary to assure participant safety?