# Endpoints which Adjudication might be recommended

- Trial characteristics
  - Pivotal Trials
  - Feasibility Trials (?)
  - Small Events of serious events
  - Key events from non premarket database
- Endpoint Characteristics
  - “soft endpoint”
  - Require clinical judgement
  - Regional, cultural variability

# Operational Issues

- Definitions
  - If possible use standard definitions
  - Definitions should be consistent across protocol, CEC charter,
  - Need for medical device standard definition integration into clinical trials
- Committee Structure
  - Independence from having an interest in the success of the trial for Pivotal trials
  - Independence might not be possible for small, specific device communities

- Committee Expertise
  - Need subspecialty for events requiring adjudication
  - Some feel the individual should be, at the least, recognized regional experts
  - There is a need for training in this area
- Event Ascertainment
  - A wide net should be cast– needed is a system to decide proper sampling vs. 100% adjudication.

# Non-Clinical Trial Data

- FDA agrees that can be made regulatory grade.
- Claims data may be able to assess outcomes equal to adjudicated outcomes in some cases.
- Cant get a deep dive about non-event issues from claims data.
- Selective adjudication process seems to be an attractive idea:
  - Risk scoring of responses to elicit a sampling group
  - Maybe should have a risk-based statistical methods for random sampling.
- Need to focus on the defining the true denominator to determine models for ascertaining true rate of complications

# Regulatory/CMS

- FDA and CMS endpoints differ.
  - CDRH– safety and effectiveness
  - CMS reasonable and necessary for dx or tx
- Parallel review reduces time between FDA marketing approval and CMS NCD
- Lack of methodology/databases to evaluate real world effectiveness.
- Develop earlier communication between developers and payers to determine and adjudicate endpoints.

- Role for adjudication to satisfy CD?
  - If early access granted, may be a role for adjudication equivalent to traditional follow up.
- When could additional effort for adjudication justify time savings for CMS CD?
  - Inclusion of representativeness of CMS beneficiaries
  - Collection of meaningful health outcomes
  - Intermediate and surrogate outcomes-- might require additional data to satisfy CMS clinical benefit