Does the Clinical Trial meet the NCD qualifying criteria for Medicare Coverage?

**STEP ONE**
Do All 3 Boxes Below Apply?

- The investigational item/service falls within a Medicare benefit category (e.g., drugs and biologics)
- Therapeutic Intent is the prominent goal. (The trial is not designed to exclusively test toxicity or pathophysiology)
- Must enroll patients with diagnosed disease (can include controls)

**If YES**

**If NO**

**STEP TWO**
Do Any of these 4 Boxes Apply?

- Trial is funded by the Government (NIH, DCD, AHRQ, CMS, DOD, or VA)
- Trial is funded by a cooperative group that receives funding from NIH, DCD, AHRQ, CMS, DOD, or VA
- Trial is conducted under an investigational new drug application (IND)
- Trial is exempt from an IND under 21 CFR 312.2(b)(1)?

**If YES**

**If NO**

**STEP THREE**
Do these 7 Boxes Apply?

- Trial potentially improves patient health outcome
- Trial is supported by Medical and clinical info
- Trial does not unjustifiably duplicate existing studies
- Trial is designed to answer the research question
- Trial is sponsored by a credible organization
- Trial is compliant with federal regulations
- Conducted according to scientific standards of integrity

**If YES**

Clinical Trial Qualifies

**If NO**

Clinical Trial DOES NOT Qualify