

CLINICAL INVESTIGATIONS UNDER MDR

PRE-MARKET
PILOT STAGE



PRE-MARKET
PIVOTAL STAGE



POST-MARKET
STAGE

TYPE OF DESIGN:
EXPLORATORY OR
CONFIRMATORY



TYPE OF DESIGN:
CONFIRMATORY



TYPE OF DESIGN:
CONFIRMATORY OR
OBSERVATIONAL

**PURPOSES/
CHARACTERISTICS:**

First in human investigation

Early feasibility for design modifications or initial data on safety, clinical performance or effectiveness

Traditional feasibility to plan and design a pivotal clinical investigation

PATIENT BURDEN:

Interventional

**PURPOSES/
CHARACTERISTICS:**

Clinical performance, effectiveness or safety for intended use based on appropriate statistical sample size and methodology

PATIENT BURDEN:

Interventional

**PURPOSES/
CHARACTERISTICS:**

Clinical performance, effectiveness or safety according to approved labeling

Clinical performance or effectiveness in border population of users

Long term outcomes or rare adverse events

PATIENT BURDEN:

Interventional

Non-interventional