# LIONBRIDGE

## 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