PRECLINICAL PHASE
DETERMINATION of the TARGET of the DRUG (organ, receptor...
PHARMACOKINETICS
- How the ORGANISM affects a DRUG
TOXICITY

DOSE LIMIT
PHARMACODYNAMIC
-
How the DRUG affects the ORGANISM
PHASE 1
1st ADMINISTRATION
in man
PHARMACOKINETICS
- How the ORGANISM affects a DRUG
STUDIES in HEALTHY VOLUNTEERS
UNIQUE DOSE
then possible
MULTIPLE ASCENDING
DOSE
1 PATIENT AT A TIME
SAFETY
A HUNDRED OF PATIENTS ENROLLED
EFFICACY
PHASE 2
MULTIPLE DOSE over time
Few Patients
Homogenous population
OPTIMUM DOSE
TOLERANCE
SEVERAL DOSES TESTED
-
COMPARISON of DOSES
LARGE NUMBER of PATIENTS
UNIQUE DOSE
PHARMACOVIGILANCE
PHASE 3
PIVOTAL TRIAL
EFFICACY
RANDOMIZED CLINICAL TRIALS
DOUBLE BLIND
VERSUS PLACEBO
REPRESENTATIVENESS - POPULATION TO TREAT
EFFICACY
CLINICAL ENDPOINT
THERAPEUTIC INTEREST
BENEFIT/RISK BALANCE
DOSSIER FOR MARKETING AUTHORIZATION
DEFINITION of the CONDITION of the MARKETING AUTHORIZATION
PHARMACO-VIGILANCE
PHARMACOVIGILANCE
SMALL NUMBER OF PATIENTS
TOXICITY STUDY
PHASE 4
POST-MA STUDIES
RARE SIDE EFFECTS DETECTION
PHARMACO-VIGILANCE
COST/EFFICACY
BENEFIT/RISK BALANCE IN « REAL LIFE »
EVALUATION of the USE of the DRUG: MISUSE, GOOD USE
REAL LIFE CONDITIONS

LARGE SCALE
BETTER UNDERSTAND THE THERAPEUTIC EFFECT of the DRUG in REAL LIFE CONDITION
OBJECTIVE:
OBTAIN THE MA
SMALL NUMBER OF PATIENTS
PHARMACOKINETICS
- How the ORGANISM affects a DRUG