Research Protocol Template

Main Investigator

Name
Address
Phone/fax
E-mail

Number of involved centers (for multi-centric studies)
Indicate the reference center

Title of the study

Protocol ID (acronym)

Keywords (up to 7 specific keywords)

Rationale

Study design

Mono-centric/multi-centric
Perspective/retrospective
Controlled/uncontrolled
Open-label/single-blinded or double-blinded
Randomized/nonrandomized
n parallel branches/n overlapped branches
Experimental/observational

Objectives

Endpoints (main primary and secondary endpoints to be listed)

Expected Results

Analyzed Criteria

Main variables/endpoints of the primary analysis
Main variables/endpoints of the secondary analysis
Safety variables
Health Economy (if applicable)

Visits and Examinations

- Therapeutic plan and goals
- Visits/controls schedule (also with graphics)
- Comparison to treatment products (if applicable)
- Dose and dosage for the study duration (if applicable)
- Formulation and power of the studied drugs (if applicable)
- Method of administration of the studied drugs (if applicable)

Informed Consent

Study Population

- Short description of the main inclusion, exclusion, and withdrawal criteria

Sample Size

Estimated Duration of the Study

Safety Advisory

Classification Needed

Requested Funds

Additional Features (based on study objectives)

References