Short Study Information

Date of the information provided: DD/MM/YYYY

Please specify/delete as necessary.

(Planned) phase-II/III-study NAME – Short Study Information	
Short study description	Open/(double)blind, randomized, placebo/active control, Intervention, study population
Primary study objective	Comparison of effectiveness and safety of intervention vs. comparator in description of study population, quality of previous specific therapy
Centers	Number of Centers, nations/continents
Size of study	Estimated number of randomized patients
Inclusion criteria	- - - -
Exclusion criteria	- - - -
Design	Parallel-group/cross over/factorial design
Randomization	N:M
Stratification	Disease severity, prior therapy, ethnicity, geographic region
Blinding	Blinding for Intervention, outcome assessment
Intervention	Substance INN, Dose, application, duration
Additional intervention	Substance INN, Dose, application, duration
Comparator	Substance INN, Dose, application, duration
Additional Comparator	Substance INN, Dose, application, duration
Start/End Date	(Planned) start and end date of patient inclusion and of study treatment. (Planned) date of analysis of primary outcome
Study periods	Duration of pre-randomization, study, post-treatment periods
Interim analyses	Methods and Procedures used
primary hypothesis to be tested	superiority/non-inf/equivalence; which arms will be compared
Endpoints / Outcome measures Please specify whether the outcomes listed in this table are appropriately controlled for multiplicity with the following symbol: (C) if controlled; (NC) if not controlled	
Primary	Primary outcome measure (and timing of assessments)
Secondary	Secondary outcome measure (and timing of assessments)
Quality of life	All QoL measures not yet listed (and timing of assessments)
supplementary	Additional outcome measure (and timing of assessments)