

STUDY PROCESS / FLOW CHART

SPECIALIZED PRECLINICAL EXPERTISE
IN MALE AND FEMALE SEXUAL FUNCTIONS
AND DISEASES OF THE LOWER URINARY TRACT

SPONSOR & PELVIPHARM INTERACTIONS AND/OR AUDIT OPPORTUNITY Feasibility assessment Communication Pilot studies of study timelines Sponsor's DATA REVIEW. Request DISCUSSION AND SECURED ARCHIVES (5) INTERPRETATION MSA CONSULTING (6) STUDY IN PROGRESS PRECLINICAL CONSULTING PROJECT FORMALIZATION STUDY END PATENT APPLICATION PUBLIC DISCLOSURE (7) Update on study Proposal of optimal Initiation at experimental design progression Pelvipharm's suggestion Unexpected situation Immediate notification to sponsor

- 1 CDA: Signature of Confidential Disclosure Agreement
- 2 MSA: Signature of Master Service Agreement
- 3 DATA REVIEW, DISCUSSION AND INTERPRETATION: Telecon and/or meeting
- 4 STUDY END : Data management
 - Standard «GLP-like» data and summary report (using sponsor's format if required)
 - Edition of original tracings, raw data and statistics (paper & numeric files)
- 5 SECURED ARCHIVES : Study proposal
 - Summary of results
 - Original tracings
 - Raw data and statistical analysis
 - Lab books
- 6 CONSULTING: Preclinical / clinical consulting
- 7 PUBLIC DISCLOSURE : If requested or applicable : Abstract presentation at scientific meetings
 - Publication in peer-reviewed journals