

FLOW CHART OF TRIAL APPROVAL

Study Management		TIME TABLE
T (-) 7	Study pre contract proposal& feasibility	>>>>
T (-) 6	Site Selection	
T (-) 5	Contract Sponsor < > CRO CRF	
T (-) 4	Contracting Site & Institutions	T ⁰ (-) 20 D
T (-) 3	Local Submission !	
T (-) 2	Local Approval	
T (-) 1	Preparing the Central Submission	T ⁰ (-) 10 D
T0	Submission of Study NEC /ANM	
T0/T1	Engaging Vendors	T0+60 D
T1	Central Submission :NEC+ANM	
T2	INVESTIGATOR MEETING	
T3	Study document Site Distribution	
T4	Study RA Approval	
T4	IMP Import & Distribution	T ⁰ + 70 D
T5	SIV (entire network initiated)	
T6	FPFV	T⁰ +80 D
T7	25% pts randomized	
Recruitment : INTERIM ANALYSIS		 Subject to Protocol DEFAULT = contingency plan
T8	50% PTS Randomized	
T9	75% Pts Randomized	
T10	100% Pts Randomized	
T11	LPLV	
T12	DM Lock [DCF]	