FLOW CHART OF TRIAL APPROVAL IN ROMANIA

WEEKS 0-5

- Sponsor conducts feasibility negotiations with CRO and provides CRO with Study Synopsis
- CRO conducts feasibility study and selects appropriate sites
- CRO obtains local administrative approval from selected sites
- CRO collects essentials documents from selected sites for the purpose of submission to the national ethics committee (NEC) and to the national committee in charge of use of experimental medication (ANM)

WEEK 6-7

- Sponsor provides CRO with final protocol and the rest of trial related documents(see infra)

WEEK 6-15

- Final protocol and trial related documents are submitted by the CRO to NEC and ANM
- Contracts are negotiated and signed
  - Sponsor with CRO
  - CRO with hospitals
  - CRO with investigators
  - CRO with vendors
- Investigator meeting takes place

WEEK 16-20

- Central approval
- Study material imported (medication, equipment, CRF)
- Study material distributed to sites
- SIV
- FPFV

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	**T^0 +80 D**
T7	**25% pts randomized**	
	Recruitment : INTERIM ANALYSIS	
T8	50% PTS Randomized	**Subject to Protocol**
T9	75% Pts Randomized	
T10	100% Pts Randomized	
T11	LPLV	
T12	DM Lock [DCF]	

DEFAULT = contingency plan

TGD Controls TT with a "hand-in " Study Management Approach , excluding TT & Budged Deviation