

Phase 1, 1/2, and 2 LOIs OEWG Timeline

OEWG timeline for opening a trial to enrollment, for Phase 1, 1/2, and 2 LOIs:

Absolute deadline: 400 days

Phase 1, 1/2, and 2 LOIs include the following:

- ETCTN and Unsolicited LOIs – phase 1, 1/2, and 2
- NCTN and Consortia phase 1, 1/2, and 2 LOIs

LOI approval stage: 60 days (Day 1 – 60)

Protocol authoring stage: 60 days (Day 60 – 120)

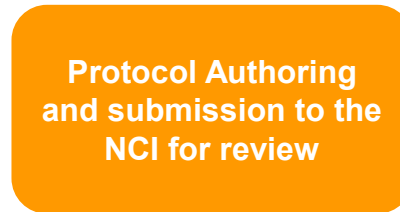
Protocol approval and open to enrollment: 280 days (Day 120 – 400)

(Please see timeline flowchart on next slide.)

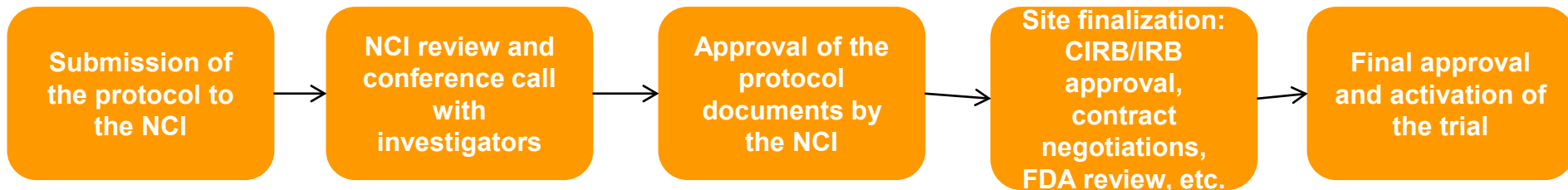
Stage 1: LOI approval
Target = 60 days



Stage 2: Protocol submission
Target = 60 days



Stage 3: Protocol Approval and Activation
Target = 280 days



Absolute deadline for opening trial to enrollment is 400 calendar days