Phase 3 Concepts
OEWG Timeline

OEWG timeline for opening a trial to enrollment, for Phase 3 Concepts:

Absolute deadline: 540 days

Phase 3 Concepts include the following:

• All Phase 3 Concepts

Concept approval stage: 90 days (Day 1 – 90)
Protocol authoring stage: 90 days (Day 90 – 180)
Protocol approval and open to enrollment: 360 days (Day 180 – 540)

(Please see flowchart timeline on next slide.)
Stage 1: Concept approval
Target = 90 days

- Initial Steering Committee review of Concept
- Consensus review and conference call with investigators
- NCI approval and if needed, pharmaceutical collaborator approval

Stage 2: Protocol submission
Target = 90 days

- Protocol authoring and submission to the NCI for review

Stage 3: Protocol Approval and Activation
Target = 360 days

- Submission of the protocol to the NCI
- NCI review and conference call with investigators
- Approval of the protocol document by the NCI
- Site finalization: CIRB approval, contract negotiations, FDA review, etc.
- Final approval and activation of the trial

Absolute deadline for opening trial to enrollment is 540 calendar days