

Clinical Trial Regulation

Belgian Pilot Project - Roche



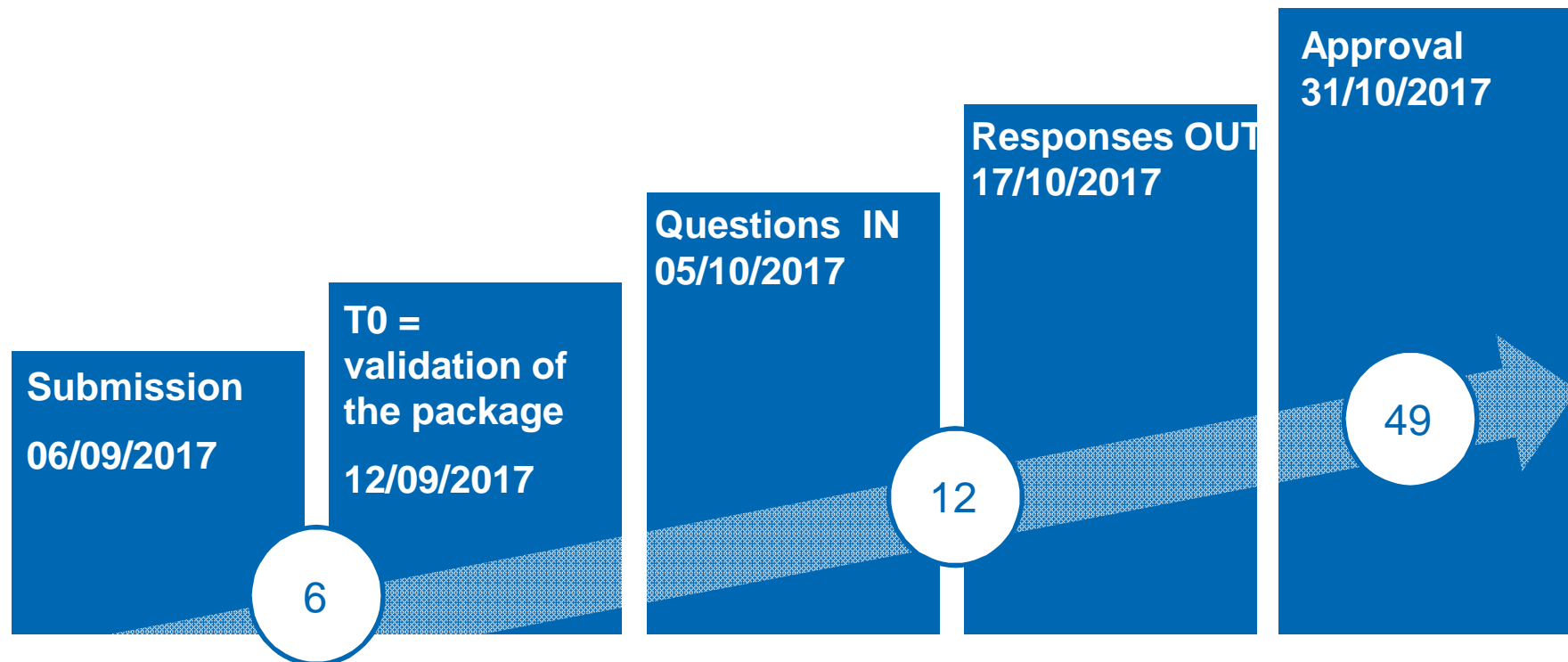
Pilot 007



- ✓ Phase III study
- ✓ 8 participating sites
- ✓ Wave II pilot



Timelines



Roche – 01/12/2017 – CTR pilot project timelines

Strengths



- ✓ Only 1 submission
- ✓ Clear guidelines - updated
- ✓ Adherence to the planned timelines
- ✓ Communication – tips and tricks
- ✓ Eudralink



Challenges



- ✓ Identity of the Ethics Committee unknown
- ✓ Suitability of the facilities – protocol
- ✓ Hospital process
- ✓ 12 days questions

Learnings from a Sponsor perspective



- ✓ Great learning
- ✓ Internal collaboration
- ✓ Global processes



Doing now what patients need next