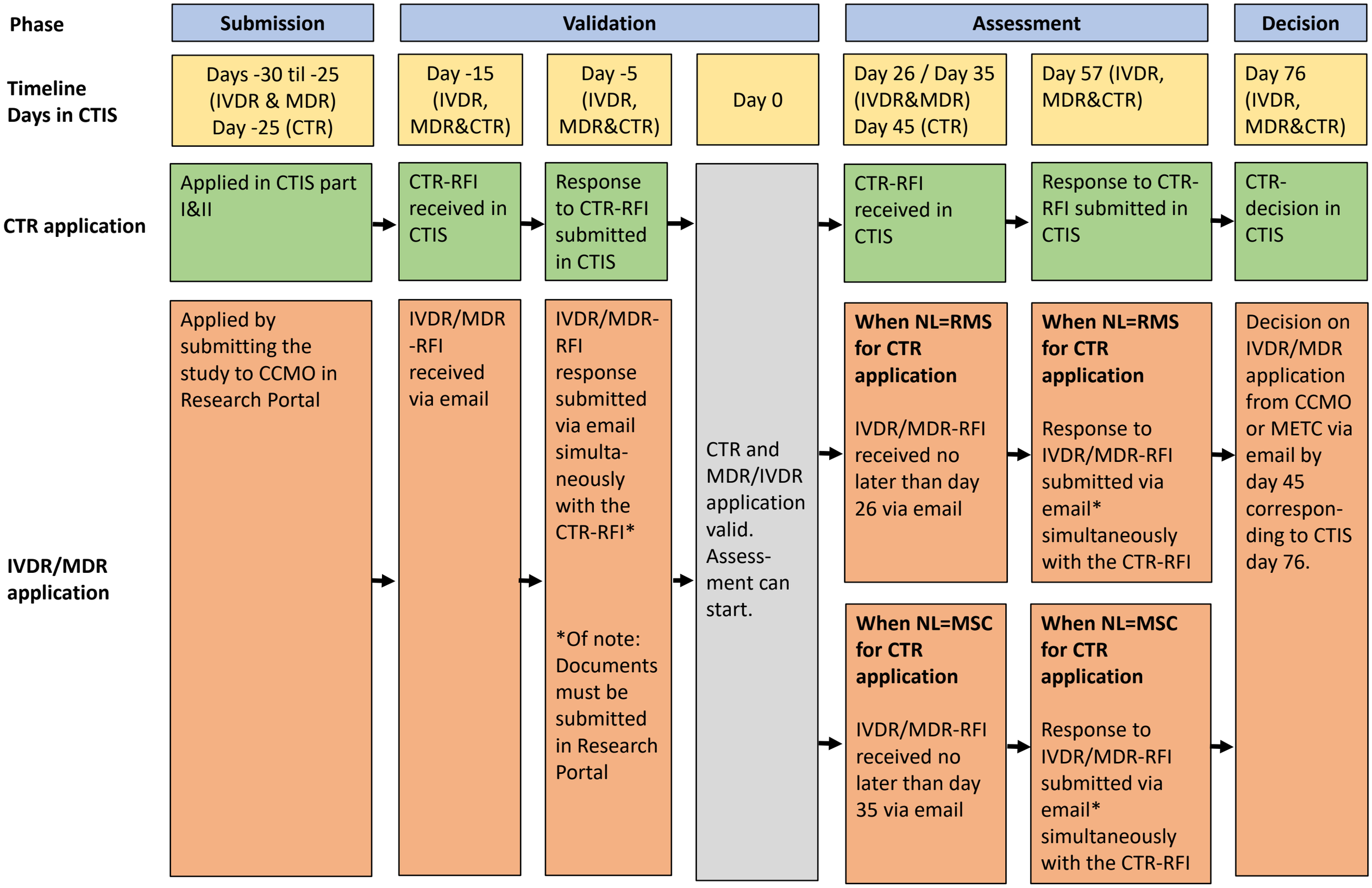
Phase
Submission
Validation
Assessment
Decision
Timeline
Days in CTIS
Days -30 til -25 (IVDR & MDR) Day -25 (CTR)
Day -15 (IVDR, MDR&CTR)
Day -5 (IVDR, MDR&CTR)
Day 0
Day 26 / Day 35 (IVDR&MDR) Day 45 (CTR)
Day 57 (IVDR, MDR&CTR)
Day 76 (IVDR, MDR&CTR)
CTR application
Applied in CTIS part I&II
CTR-RFI received in CTIS
Response to CTR-RFI submitted in CTIS
CTR-RFI received in CTIS
Response to CTR-RFI submitted in CTIS
CTR-decision in CTIS
IVDR/MDR application
Applied by submitting the study to CCMO in Research Portal
IVDR/MDR -RFI received via email
IVDR/MDR-RFI response submitted via email simulta-neously with the CTR-RFI*
*Of note: Documents must be submitted in Research Portal
CTR and MDR/IVDR application valid. Assess-ment can start.
When NL=RMS for CTR application
IVDR/MDR-RFI received no later than day 26 via email
When NL=RMS for CTR application
Response to IVDR/MDR-RFI submitted via email* simultaneously with the CTR-RFI
When NL=MSC for CTR application
IVDR/MDR-RFI received no later than day 35 via email
When NL=MSC for CTR application
Response to IVDR/MDR-RFI submitted via email* simultaneously with the CTR-RFI
Decision on IVDR/MDR application from CCMO or METC via email by day 45 correspon-ding to CTIS day 76.