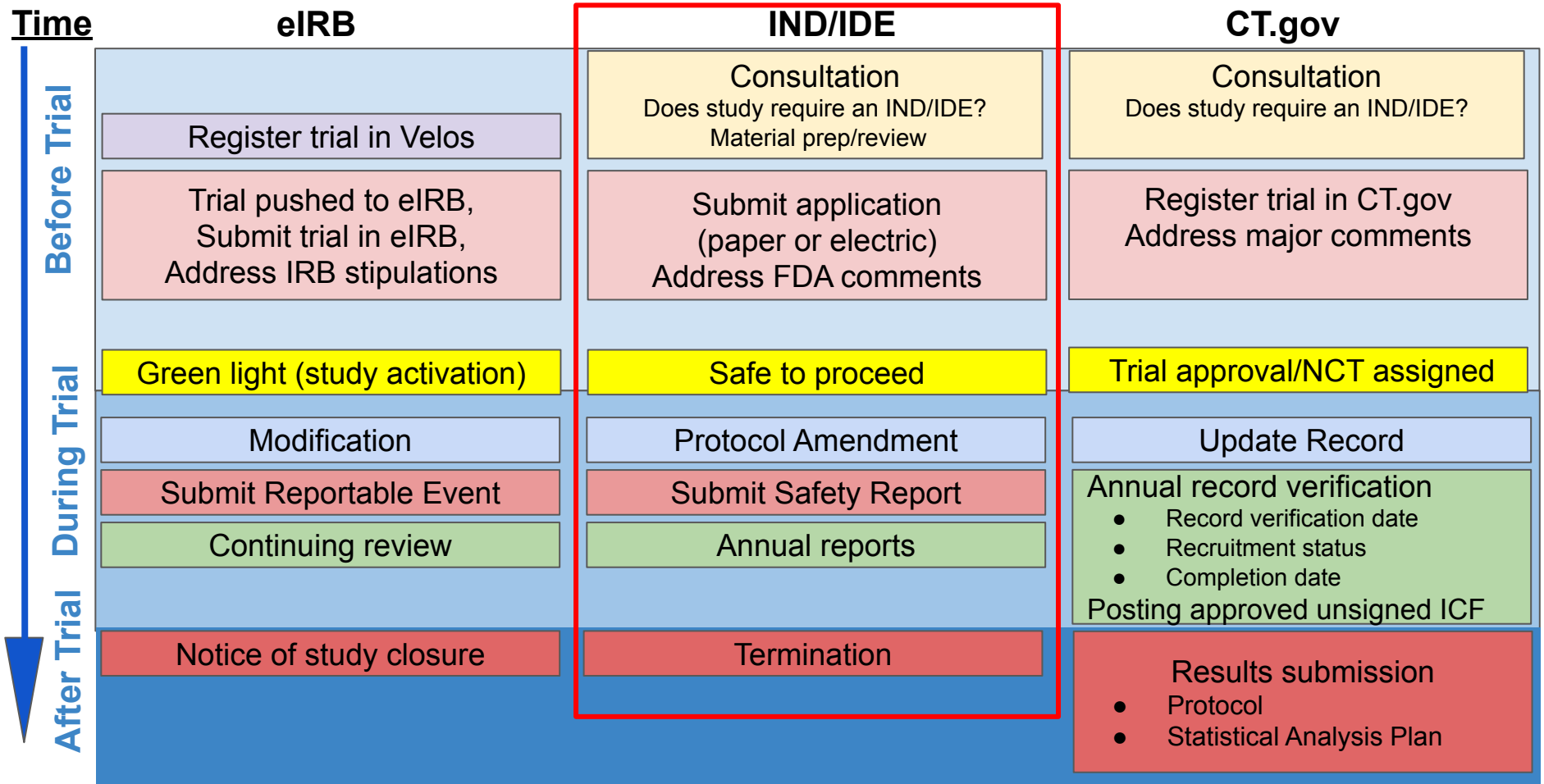
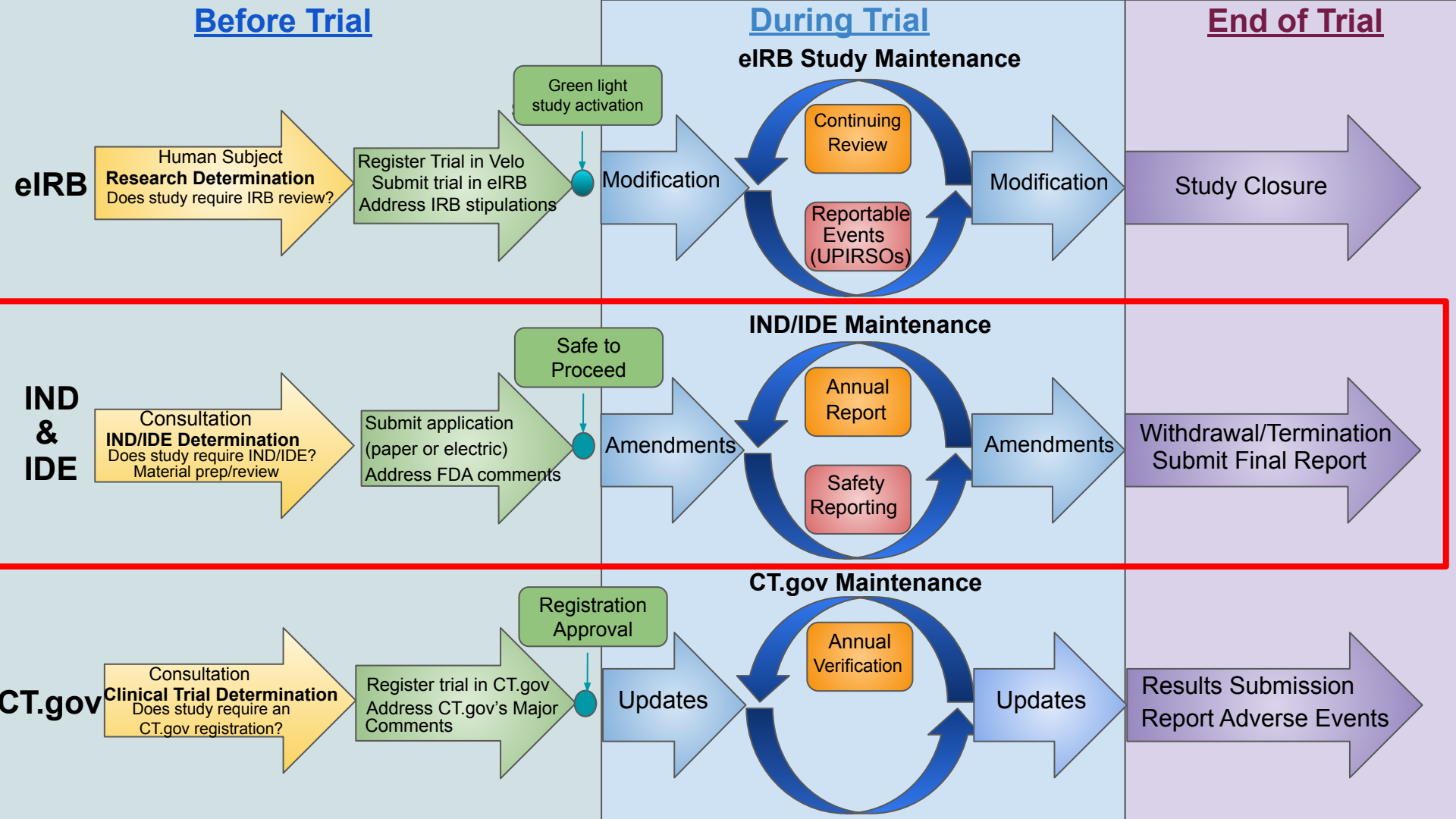
IND/IDE, eIRB and CT.gov clinical trial timeline




Before Trial
During Trial
End of Trial
eIRB Study Maintenance
eIRB
Human Subject
Research Determination
Does study require IRB review?
Register Trial in Velo
Submit trial in eIRB
Address IRB stipulations
Green light
study activation
Modification
Continuing
Review
Reportable
Events
(UPIRSOs)
Modification
Study Closure
IND/IDE Maintenance
IND
&
IDE
Consultation
IND/IDE Determination
Does study require IND/IDE?
Material prep/review
Submit application
(paper or electric)
Address FDA comments
Safe to
Proceed
Amendments
Annual
Report
Safety
Reporting
Amendments
Withdrawal/Termination
Submit Final Report
CT.gov Maintenance
CT.gov
Consultation
Clinical Trial Determination
Does study require an
CT.gov registration?
Register trial in CT.gov
Address CT.gov's Major
Comments
Registration
Approval
Updates
Annual
Verification
Updates
Results Submission
Report Adverse Events