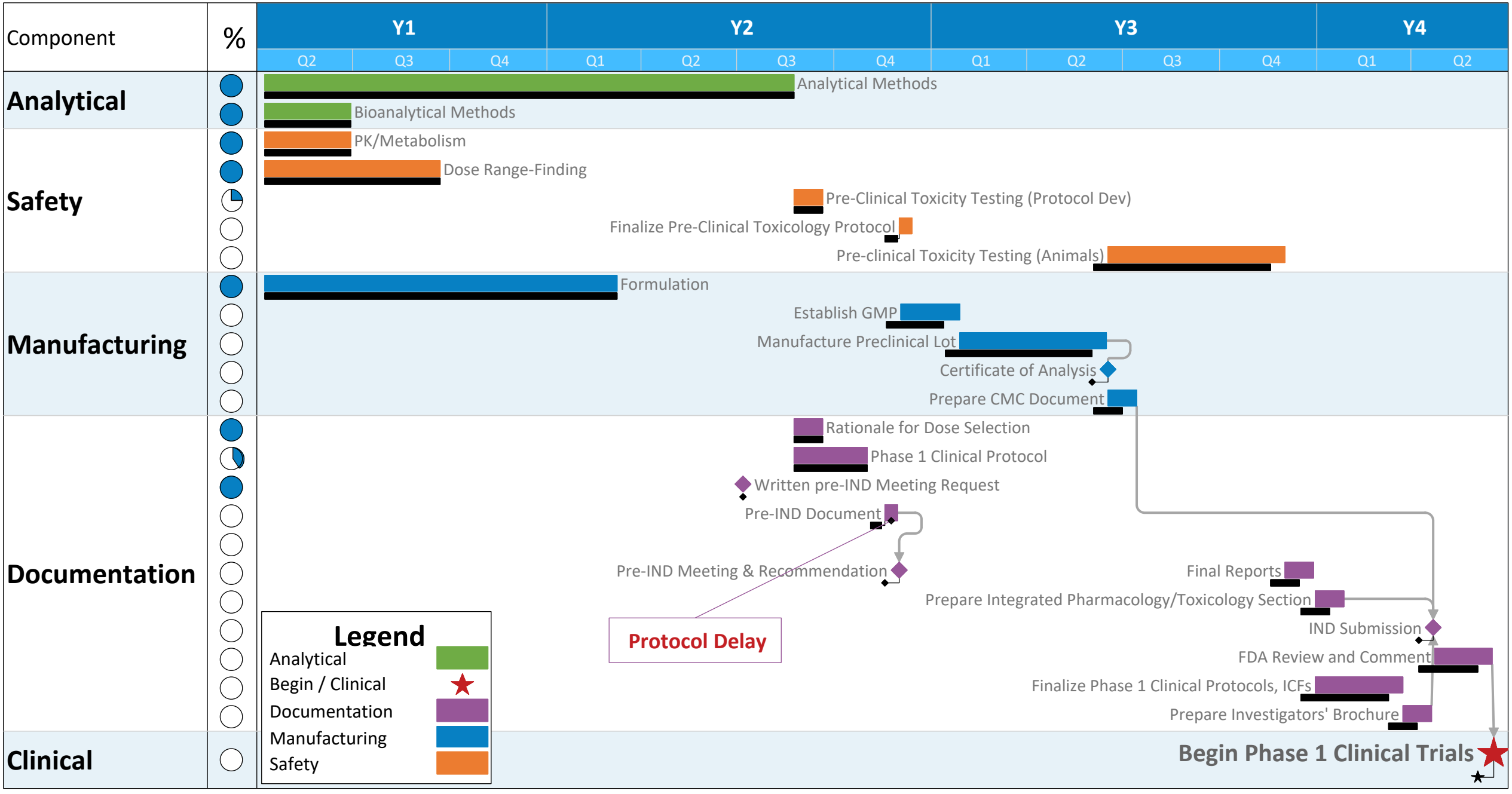
Component
%
Y1
Y2
Y3
Y4
Q2
Q3
Q4
Q1
Q2
Q3
Q4
Q1
Q2
Q3
Q4
Q1
Q2
Analytical
Analytical Methods
Bioanalytical Methods
Safety
PK/Metabolism
Dose Range-Finding
Pre-Clinical Toxicity Testing (Protocol Dev)
Finalize Pre-Clinical Toxicology Protocol
Pre-clinical Toxicity Testing (Animals)
Manufacturing
Formulation
Establish GMP
Manufacture Preclinical Lot
Certificate of Analysis
Prepare CMC Document
Documentation
Rationale for Dose Selection
Phase 1 Clinical Protocol
Written pre-IND Meeting Request
Pre-IND Document
Pre-IND Meeting & Recommendation
Protocol Delay
Final Reports
Prepare Integrated Pharmacology/Toxicology Section
IND Submission
FDA Review and Comment
Finalize Phase 1 Clinical Protocols, ICFs
Prepare Investigators' Brochure
Legend
Analytical
Begin / Clinical
Documentation
Manufacturing
Safety
Clinical
Begin Phase 1 Clinical Trials