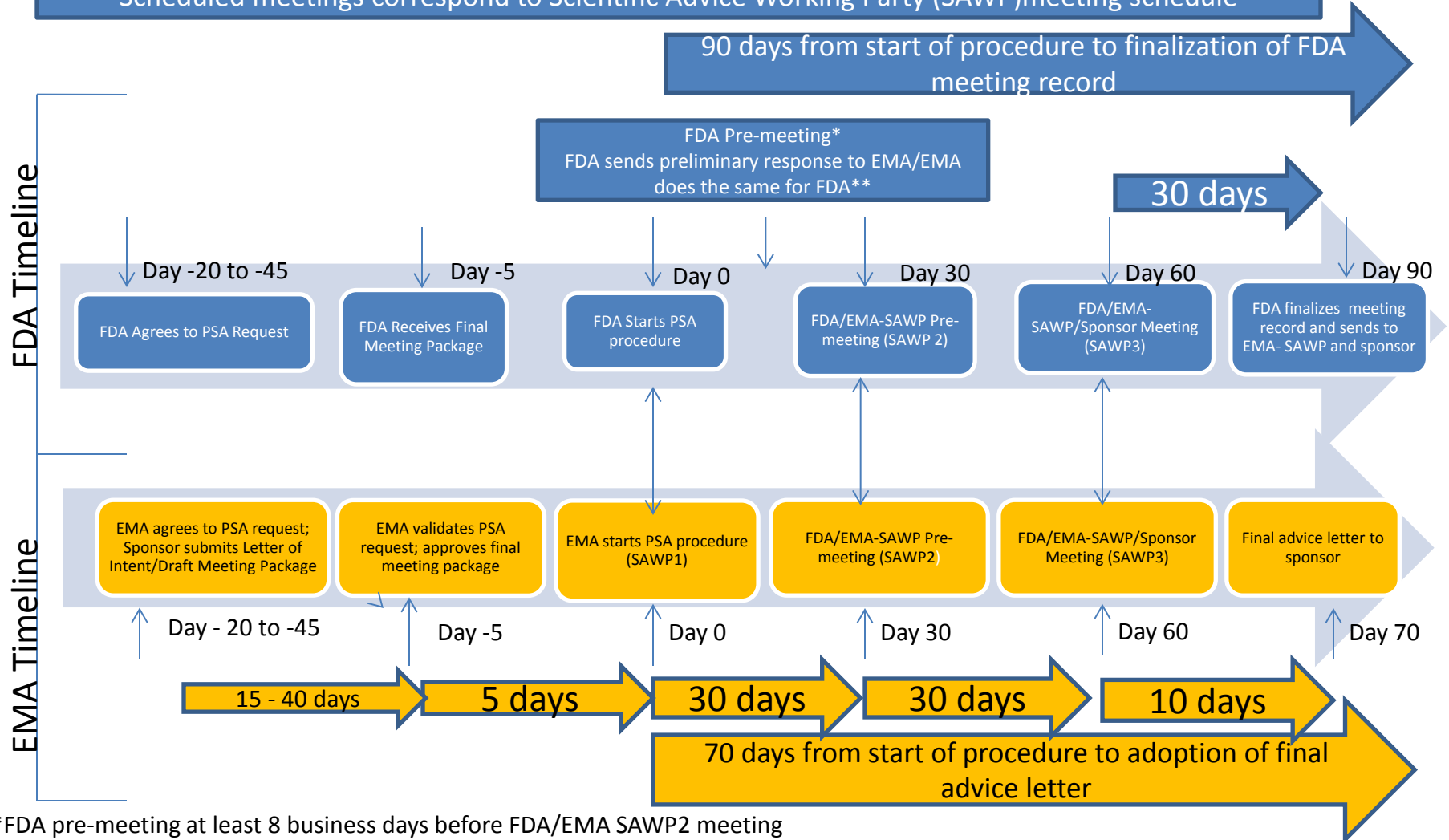


Parallel Scientific Advice (FDA-EMA)

PSA does not follow PDUFA or BsUFA meeting timelines.

Preparatory time to initiate process is 2-3 months; schedule below is an estimate.

****Scheduled meetings correspond to Scientific Advice Working Party (SAWP) meeting schedule****



*FDA pre-meeting at least 8 business days before FDA/EMA SAWP2 meeting

**FDA sends preliminary response to EMA/SAWP 2-3 days before FDA/EMA SAWP2 meeting

PSA Timeline Chart*

Day	FDA	EMA
Anytime	Sponsor submits informal request for Parallel Scientific Advice to FDA and EMA	
Day -20 to -45	FDA agrees to informal PSA request; Sponsor submits formal PSA request to FDA.	EMA agrees to informal PSA request; Sponsor submits letter of intent (formal PSA request) and draft package
Day 0 to -24		EMA reviews draft package; appoints coordinator
Day -5	FDA receives final meeting package	EMA validates PSA request; approves final meeting package
Day 0	FDA PSA process starts	EMA PSA process starts (SAWP1)
Day 15-20	FDA pre-meeting	
Day 25-28	FDA sends preliminary responses to EMA	EMA sends preliminary responses to FDA
Day 30	Joint FDA/EMA meeting (SAWP2)**	Joint FDA/EMA meeting (SAWP2)
Day 60	Sponsor/FDA/EMA meeting (SAWP3)	Sponsor/FDA/EMA meeting (SAWP3)
Day 70 to 90	FDA issues final meeting record (day 90 for FDA)	EMA issues final advice letter (day 70 for EMA)

*PSA does not follow PDUFA or BSuFA meeting timelines. Preparatory time to initiate process is 2-3 months; schedule above is an estimate. Scheduled meetings correspond to Scientific Advice Working Party (SAWP) meeting schedule.

**Best Practice: FDA and EMA develop a list of common issues/answers to questions. Both agencies send to sponsor preliminary common issues (EMA)/answers to questions (FDA). Sponsor sends in a revised proposal and meeting package prior to SAWP3.