

EMA-FDA Parallel Scientific Advice (PSA) Timetable

| Day | FDA | EMA |
|--------------|---|---|
| Anytime | Sponsor submits request for PSA to FDA and EMA Agencies decline → no PSA Agencies accept → Sponsor begins drafting meeting package according to SAWP procedures | |
| Varies | | Meeting Package Submission and Validation Phase; Option for preparatory meeting with EMA according to SAWP procedures |
| Day 0 | EMA validates meeting package; FDA receives validated meeting package; Procedure begins | |
| Day 15-25 | FDA internal meeting | EMA SAWP internal discussion |
| Day 30-34 | FDA sends Preliminary Comments to EMA | EMA sends List of Issues to FDA |
| Day 35 | Bilateral FDA/EMA meeting | |
| Day 65 | Trilateral Sponsor/FDA/EMA meeting | |
| Day 75 to 95 | FDA issues final meeting minutes (30 days after trilateral) | EMA issues final advice letter (10 days after trilateral) |