

# Overview of FDA-EMA Parallel Scientific Advice Program for The Center for Biologics Evaluation and Research (CBER)

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# Purpose

- The Parallel Scientific Advice (PSA) Program provides a concurrent review and exchange of advice from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to sponsors on scientific issues during the development phase of new medicinal products (i.e., new human drugs and biologics).

# Learning Objectives

- Discuss the FDA-EMA PSA agreement
- Identify the best candidates and eligible products
- Identify the benefits to PSA interactions/meetings
- Learn how to submit a request for PSA
- Identify the information in a PSA request
- Review the estimated timeline for a PSA
- Understand the process and how PSA meeting requests are managed in CBER

# Background



- 2004- FDA/EMA PSA Pilot Program Agreement
- 2005- Pilot Program Initiated
- 2006- Indefinite Extension of the PSA Program
- 2020- Revision of CBER SOPP 8001.6

# Basic Guidelines for PSA

- PSA process is voluntary
- Initiated at the sponsor's request
- Intended to address a single set of questions
- Not viewed as an ongoing series of consultations
- Focus on specific questions or issues involving the development of an eligible product

# Basic Guidelines for PSA



- Not subject to performance goals of Prescription Drug User Fee Act (PDUFA) meetings
- Similar to a Pre-IND Type-B Meeting
- Corresponds to 70-day timeline of EMA Scientific Working Party (SAWP)

# Best Candidates for PSA



- Pre-IND or End of Phase II
- Important medicinal products (unmet medical needs)
- Indications lacking development guidelines, or significantly different guidelines for FDA/EMA
- Biosimilars or products with significant clinical safety, animal toxicology, or unique manufacturing concerns
- Rare diseases and special populations

# FDA-EMA PSA Agreement



- Confidentiality Arrangement between FDA/EMA
- Commitment to Review Goals/Timelines
- Does not adversely impact performance expectations



# Eligible CBER Products

- Cell Therapies
- Gene Therapies
- Tissue Engineered
- Vaccines
- Plasma Derivatives

# Benefits of PSA

- Increased dialogue between the agencies and sponsors at various points of the life cycle of a new product
- A better understanding of the foundations of scientific advice
- An opportunity to advance/optimize product development
- Reduce and avoid unnecessary replication of testing or divergence in testing methodologies
- A single meeting package saves time and resources

# Submitting a PSA Request

- Send a single “Request for PSA” Letter to:
  - [emainternational@ema.europa.eu](mailto:emainternational@ema.europa.eu)
  - [US-FDA-EUR@fda.hhs.gov](mailto:US-FDA-EUR@fda.hhs.gov)

# Information in PSA Request



1. Product in development
2. Explanation of why a discussion with FDA/EMA is beneficial to the product's development
3. Specific questions requiring clarification
4. Goals for the meeting
5. Explicit Authorization for FDA/EMA exchange of information

# PSA Request Guidelines



- A request does not guarantee granting of PSA
- One or both agencies may decline participation
- PSA not granted-Sponsor can request advice separately

# Involved Parties



- Senior Advisor for International Affairs (SAIA) (FDA)
- Foreign Regulatory Communications Coordinator (FRCC) (FDA)
- Product Office Lead (Regulatory Project Manager-RPM) (FDA)
- FDA/CBER Review Team
- EMA POC, Assessors/ Scientific Advice Working Party (SAWP)
- Sponsor
- Two patient representatives

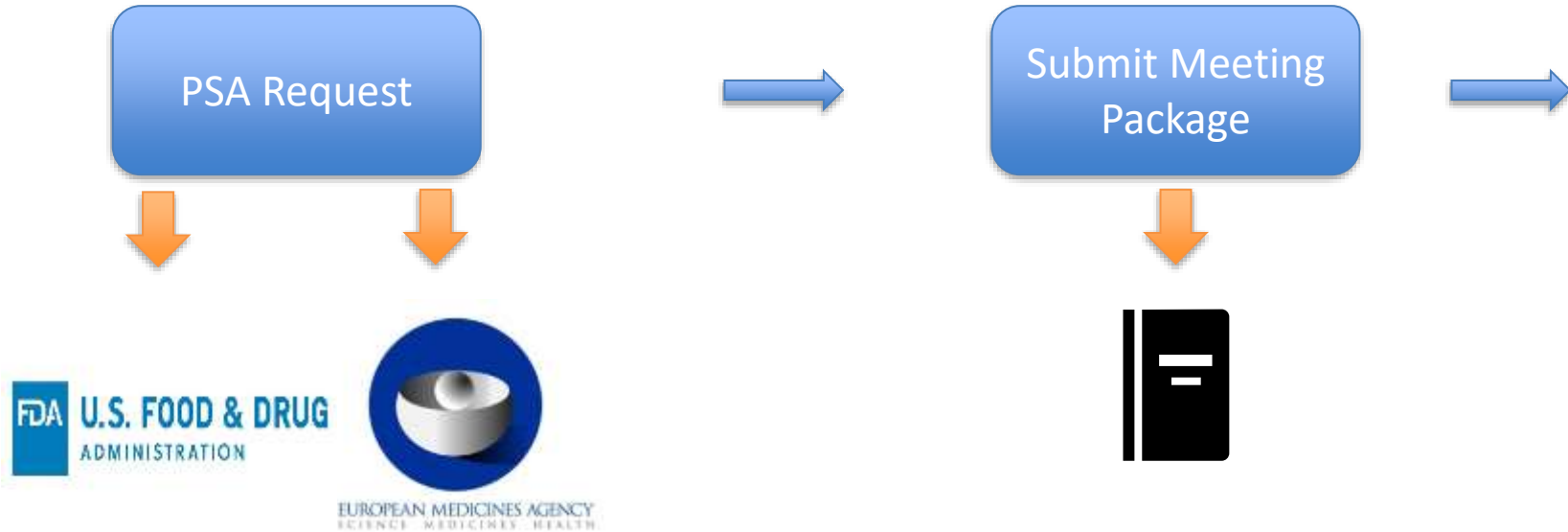
# PSA Timeline\*



Day	FDA	EMA
Anytime	Sponsor submits informal request for Parallel Scientific Advice to FDA and EMA; Agencies decline, no PSA; Agencies accept, Sponsor begins drafting meeting package according to SAWP procedures	
Day -1 to -45		Meeting Package and Validation Phase; Option for prep meeting with EMA per SAWP procedures
<b>Day 0</b>	FDA receives validated meeting package	EMA validates meeting package
Day 5		EMA procedure begins (SAWP1)
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 (SAWP2)	Bilateral FDA/EMA meeting (SAWP2)
Day 65	Trilateral Sponsor/FDA/EMA meeting (SAWP3)	Trilateral Sponsor/FDA/EMA meeting (SAWP3)
Day 75 to 95	FDA issues final meeting minutes (30 days after trilateral)	EMA issues final advice letter (10 days after trilateral)

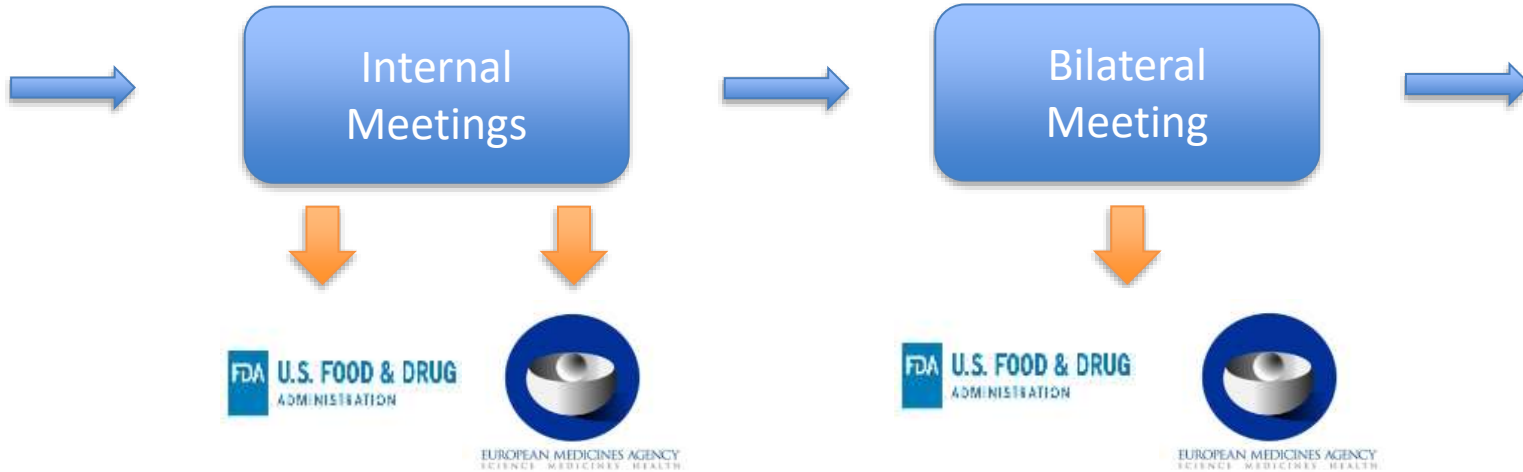
\*PSA does not follow PDUFA or BSuFA meeting timelines. Preparatory time to initiate process is 2-3 months; schedule above is an estimate. Scheduled meetings correspond to Scientific Advice Working Party (SAWP) meeting schedule.

# PSA Process

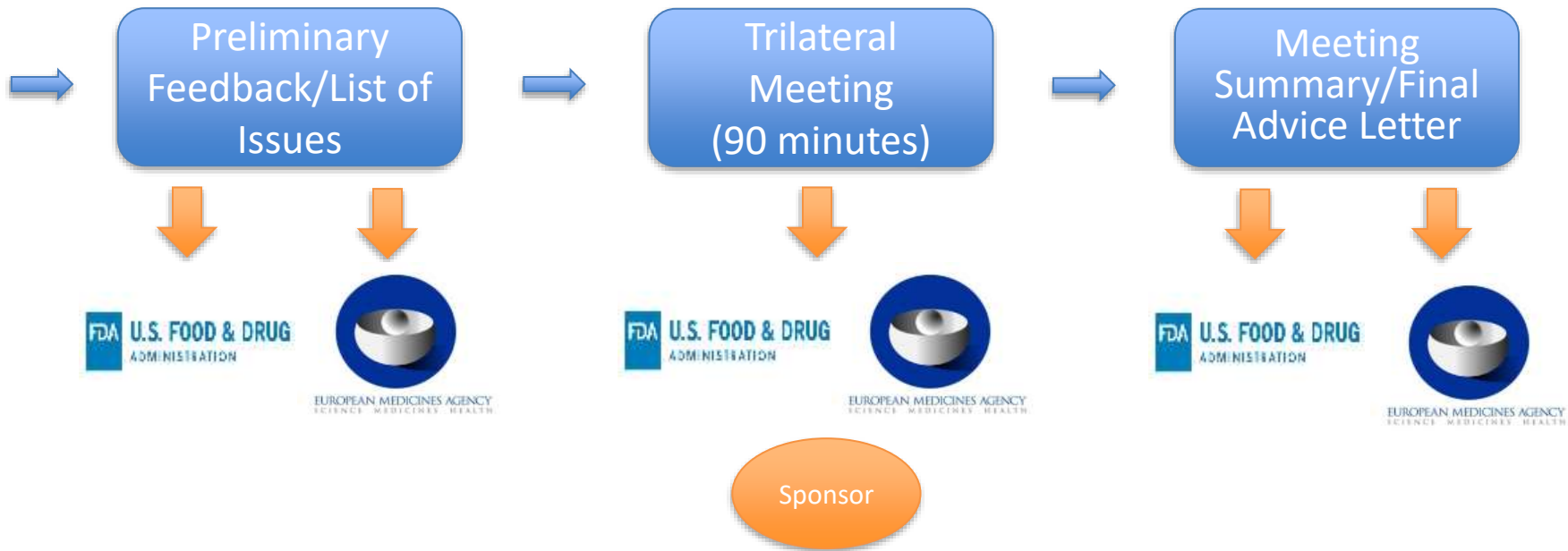




# PSA Process



# PSA Process



# PSA Advice

- Each agency will provide independent advice
- Advice of each agency may differ
- Recommendations regarding drug development issues may differ
- Marketing application decisions may differ
- Both agencies strive to provide convergent responses

# Best Practices

- PSA should not be the first encounter with FDA
- Understanding and flexibility of timelines
- Ensure the appropriateness of a PSA request
- A single PSA request submitted separately
- Meeting packages should be complete
- Be well prepared for the Trilateral meeting

# Summary

- Sponsors should have a clear understanding of the agencies' requirements and perspectives
- Advice to sponsors promotes product development globally
- Not intended to provide combined or joint advice
- An opportunity for increased dialogue and possible convergence between agencies
- Each Agency provides independent advice separately

# Challenge Question #1

**The PSA Trilateral Meeting occurs approximately how many days after receiving the meeting package?**

- A. 14 days
- B. 30 days
- C. 60 days
- D. 90 days

# Challenge Question #2

Which of the following statements is NOT true?

- A. The PSA process is voluntary
- B. PSA is viewed as an ongoing series of consultations
- C. PSA is initiated at the sponsor's request
- D. PSA is intended to address a single set of questions
- E. PSA can be initiated by EMA or FDA in cooperation with the sponsor

# Resources



- FDA link for [General Principles EMA-FDA Parallel Scientific Advice \(Human Medicinal Products\)](#)
- EMA link for [General Principles EMA-FDA Parallel Scientific Advice \(Human Medicinal Products\)](#)[External Link Disclaimer](#)
- [European Medicines Agency Guidance for Applicants seeking scientific advice and protocol assistance](#)
- General Principles for PSA document  
<https://www.fda.gov/media/105211/download>
- Send a Request for PSA Letter to [emainternational@ema.europa.eu](mailto:emainternational@ema.europa.eu) at EMA and [US-FDA-EUR@fda.hhs.gov](mailto:US-FDA-EUR@fda.hhs.gov) at FDA.



# Closing Thought



*Eligible Sponsors seeking Global Drug Development should submit a request for Parallel Scientific Advice*

# Questions?

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