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SCIENCE MEDICINES HEALTH

EMA/FDA Parallel Scientific Advice (PSA)

CAT Interested Parties meeting with Industry

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What is Parallel Scientific Advice (PSA)?

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A mechanism where **EMA and FDA concurrently exchange their views on scientific issues with the sponsor**:

- Increase dialogue early in product lifecycle
- Deepen understanding of regulatory decisions
- Optimize development
- Avoid unnecessary testing

Conducted under Confidentiality Arrangements

The **best candidates** for PSA:

- Important medicinal products (e.g. unmet medical needs)
- Indications lacking development guidelines, or significantly different guidelines

Parallel EMA-FDA Scientific Advice

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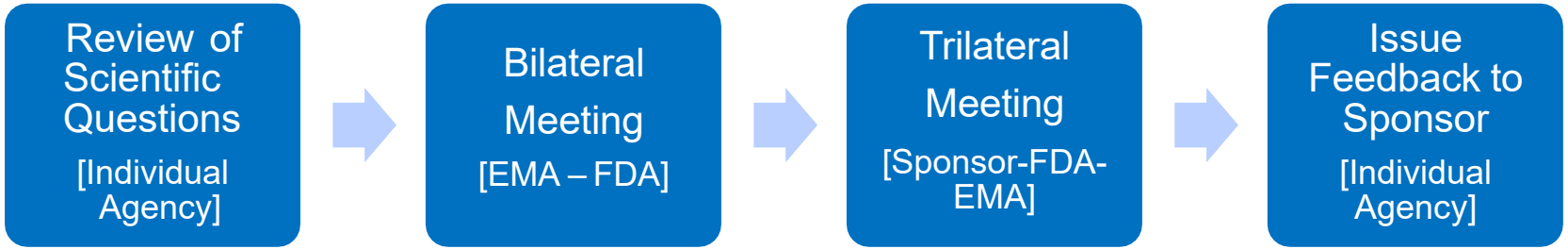
- Voluntary, at request of sponsor
- Usually accepted for priority product or one with significant development challenges, and especially if limited clinical trial opportunities, such as rare disease
- Questions on product development put both to EMA and FDA
- Scientific advice can be provided on any scientific question
- Advice can be asked only for a specific part of the development
- At any time point of the development
- Discussions between EMA-FDA, and joint discussion with sponsor
- Agencies issue own responses to sponsor’s questions in line with usual procedures

Overview of Collaboration



How to apply?

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- A single "Request for PSA" letter sent to both FDA and EMA
  - Email: emainternational@ema.europa.eu
  - Email: US-FDA-EUR@fda.hhs.gov
- Letter should include:
  - the product in development
  - why a discussion with both FDA and EMA would be beneficial
  - specific questions requiring clarification
  - desired goals for the meeting
  - explicit authorization for the agencies' comprehensive exchange of all information relevant to the product

Will a PSA request be granted?

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- A PSA request does not guarantee the PSA procedure will be granted
- For various reasons, one or both agencies may decline to participate in such a procedure
- If request not granted:
  - Sponsor can still pursue a SA procedure with each Agency individually
  - Or consultative advice *(experts from one Agency will be invited to participate in the discussions of the other Agency)*

What gets submitted to the Agencies?

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- PSA request
- Meeting package
- Answers to information requests / List of Questions
- Presentation for trilateral meeting
- Minutes of trilateral meeting

The overall process for PSA is aligned with CHMP Scientific Advice (SA) procedure (70-day timeline) and timeline for Type B Meeting at FDA

Timeline and Process

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Day	Sponsor	FDA	EMA
Day -45 to -20	Sponsor submits To FDA: PSA request To EMA: PSA request; if accepted- draft package	FDA agrees to PSA request	EMA agrees to PSA request
Day -20 to -5			EMA reviews draft package and provides feedback
Day -5	Sponsor submits final meeting package	FDA receives validated meeting package	EMA validates package
Day 0		FDA PSA process starts	EMA PSA process starts (SAWP1)
Day 20		FDA pre-meeting/Preliminary Comments drafted	
Day 30			SAWP2/List of Issues drafted
Day 31		EMA/FDA exchange Preliminary Comments/List of Issues	
Day 32-37		Bilateral FDA/EMA meeting (days after SAWP2)	
Day 60	Sponsor/FDA/EMA Trilateral meeting (SAWP3)		
Day 70 – 90	Sponsor submits meeting minutes to EMA	FDA sends final meeting minutes to Sponsor and EMA	EMA issues final advice letter to Sponsor and sends to FDA

PSA Benefits

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- Opportunity for engagement with both regulatory agencies
- Avoid duplication of work
- Common approach where feasible or better understanding of the reasons for potentially remaining divergences
- Opportunity to simultaneously solicit and receive "official" feedback
- '*Both agencies will strive to provide PSA responses that are convergent*' *(PSA General Principles)*

PSA Five Year Review: 2016-2020

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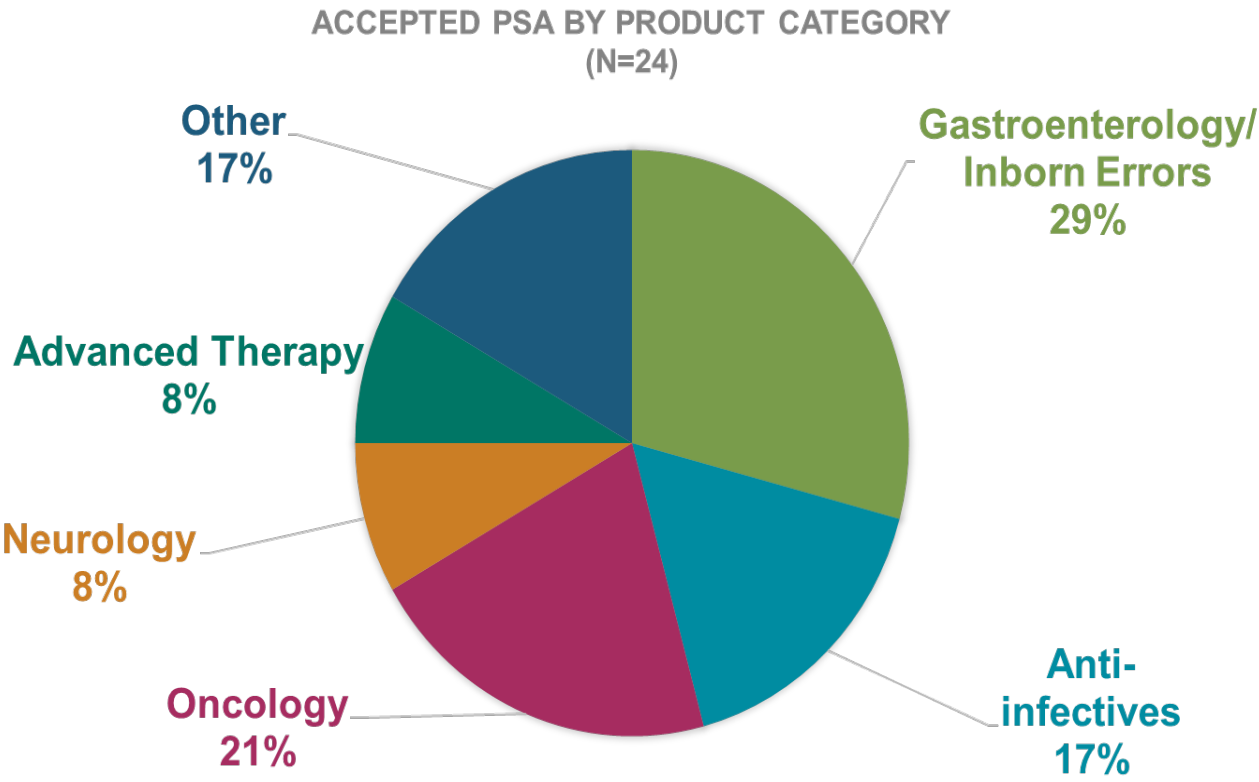
Total Requests	32
Accepted Requests	24 (75%)
Denied Requests	8
Withdrawn/ Package not Submitted	4
Completed Procedures	20



Further information

General Principles for EMA-FDA PSA document:

https://www.ema.europa.eu/en/documents/other/general-principles-european-medicines-agency-food-drug-administration-parallel-scientific-advice_en.pdf

Any questions?

Further information

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