

# **Considering a PSA Request?**

## **Summary and Best Practices**

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# Challenge Question 1



# Parallel Scientific Advice

## PSA 101

### It Is

- Scientific advice on product development to support a global program
- Mechanism that brings two regulators to the table simultaneously
- Opportunity to learn how aligned they are

### It Is Not

- Guarantee of FDA and EMA alignment
- A substitute for sound scientific planning
- The end of the story



General Principles for PSA document

<https://www.fda.gov/media/105211/download>

# Challenge Question 2



# Myths abound

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- Timelines are within expected for similar processes
- Most variability in timelines depends on applicants and how long it takes between initial inquiry and a sound briefing book
- Once the process is underway you will be able to predict when you will have your advice



# Challenge Question 3



# Experience tells the story



# Best Practices 1:

## Timing matters

- PSA should not be your first discussion with FDA on development
  - Prior pre-IND or IND
  - Allows PSA to focus on global development
- Factor in calendar
  - Agencies' timelines reliable
  - Expect 2 weeks to reply to informal request
  - August recess of SAWP





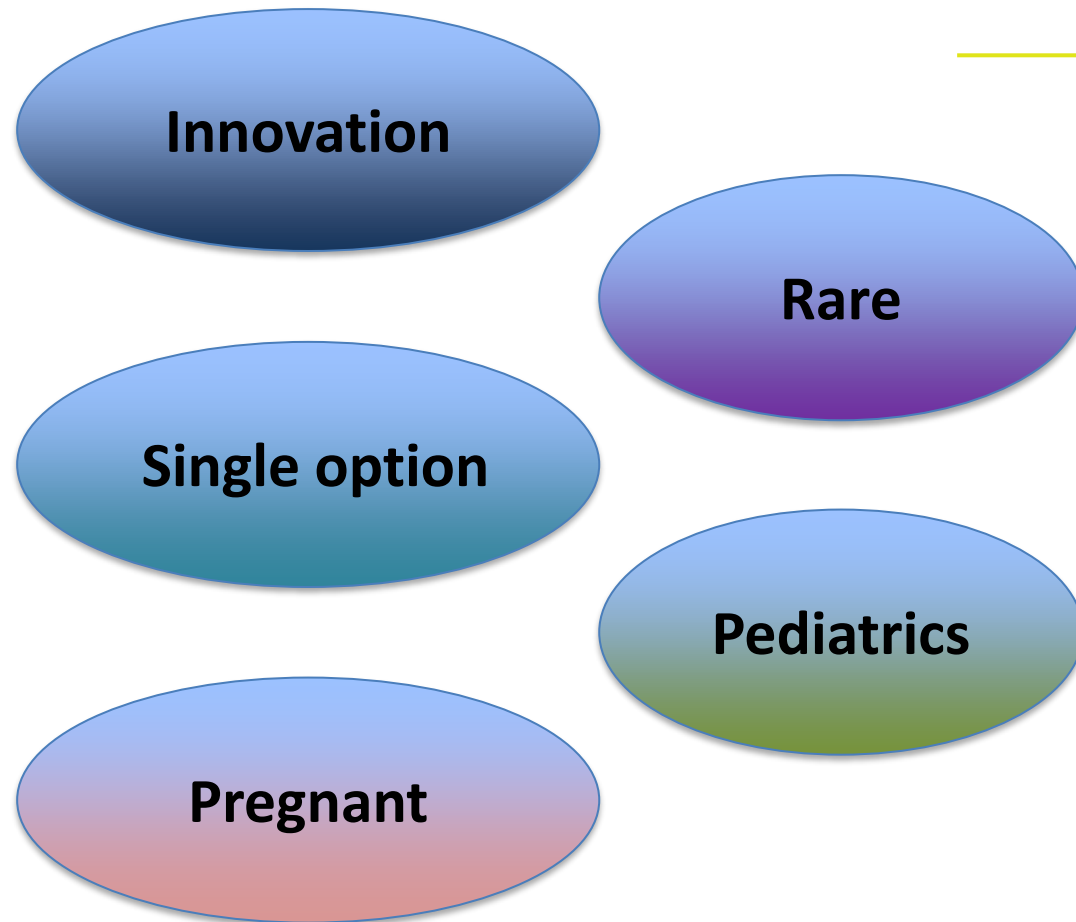
## Best Practices 2: Best candidates

- Check FDA and EMA guidelines
  - If agencies already aligned PSA may not have added value
- Best candidates
  - Innovative products
  - New science
  - Novel regulatory concepts

# Best Practices 3:

## Make the case for public health value

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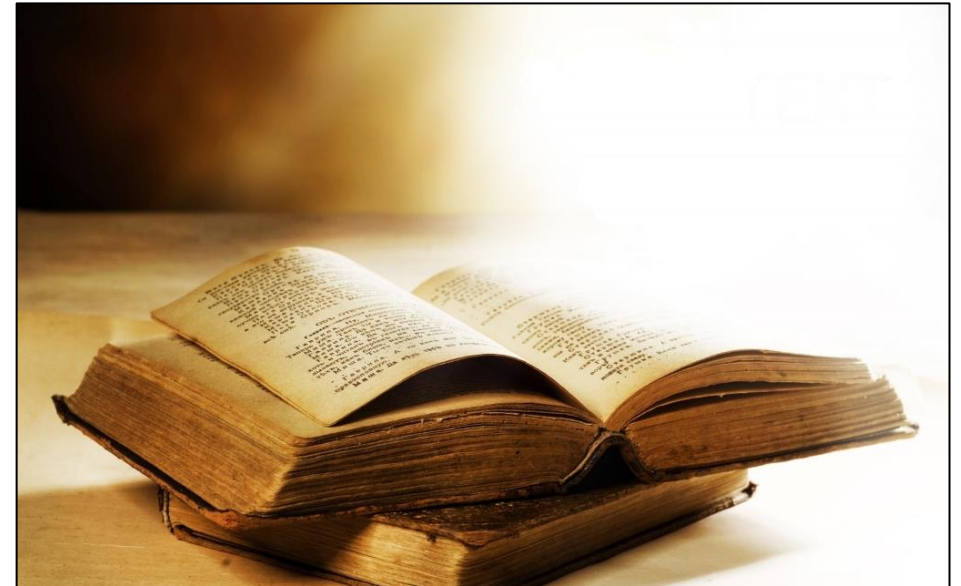


- Unmet medical need
- Rare diseases
- Special populations
- Explain product potential
- Be specific!

# Best Practices 4:

## Briefing materials – Do the homework

- Single book for both agencies essential
  - CHMP Scientific Advice template is option
- Be clear on priorities
- Think through all issues and options – and then be transparent about plans
- Indicate if questions are for one Agency or both



# Best Practices 5: The Trilateral Meeting



- Prepare well
- Use preliminary feedback
- Prioritize
- Foster discussion
- Prepare

