U.S. FOOD & DRUG ADMINISTRATION

Thoughts from a Decision-Maker (One of Many)

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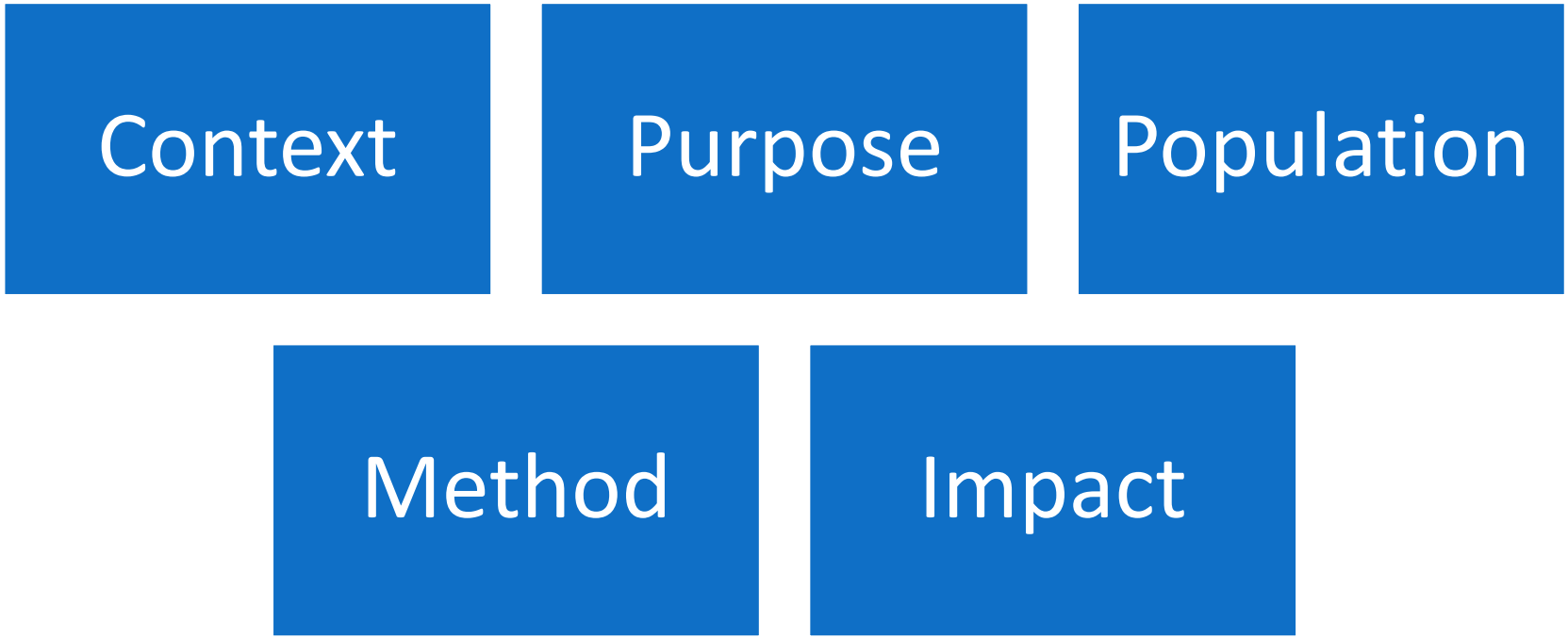
The views expressed in this presentation are those of the speaker, and do not necessarily represent an official FDA position

ISPOR Framework



Considerations

FOCUS ON THE PURPOSE

WHAT DOES THE DECISION MAKER NEED AND WHAT WILL THEY FIND USEFUL

BUDGET TIME TO TALK TO DECISION-MAKERS (REGULATOR, HTA, ETC.)

Context, Purpose, Impact

Talk to your expert consultants before talking to the decision-maker [do not delay talking directly to the decision makers]

There is a lot of other information a decision-maker is also considering

Excellent study not relevant to our questions

https://www.fda.gov/about-fda/cdrh-patient-science-and-engagement-program/patient-preference-information-ppi-medical-device-decision-making

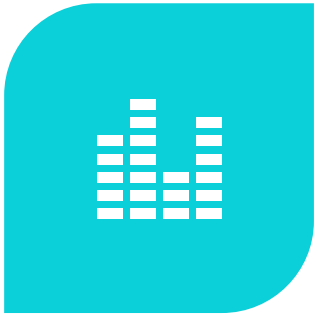
https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development

Thoughts Beyond "Come Talk to Us"

- Not just the answer or the results
  - Justify decisions
    - What compromises were made? Why?
    - Documentation
    - Decide not to do the study? Why?
- If you want comments on your study, ask a question about it
  - [CDER: might be a WRO Type C meeting]
  - [CDRH: pre-submission process; CDRH Patient Science & Engagement team]
  - Submit the protocol (with a question)
  - CRO? Consultant?
    - Ask for the exact comments/advice letter from FDA/the decision-maker
  - "Strongly recommend" "Recommend"
- Do not need to do everything in one study

Helpful Questions

WHO MAKES THE DECISION?



WHAT ARE THEY WEIGHING AND WHY?

WILL YOUR STUDY HELP THEM MAKE THE DECISION THEY NEED TO MAKE?

Participants' Time Matters: Use methods that can answer the questions decision makers are trying to answer

PURPOSE

PRINCIPLES

SCIENCE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