

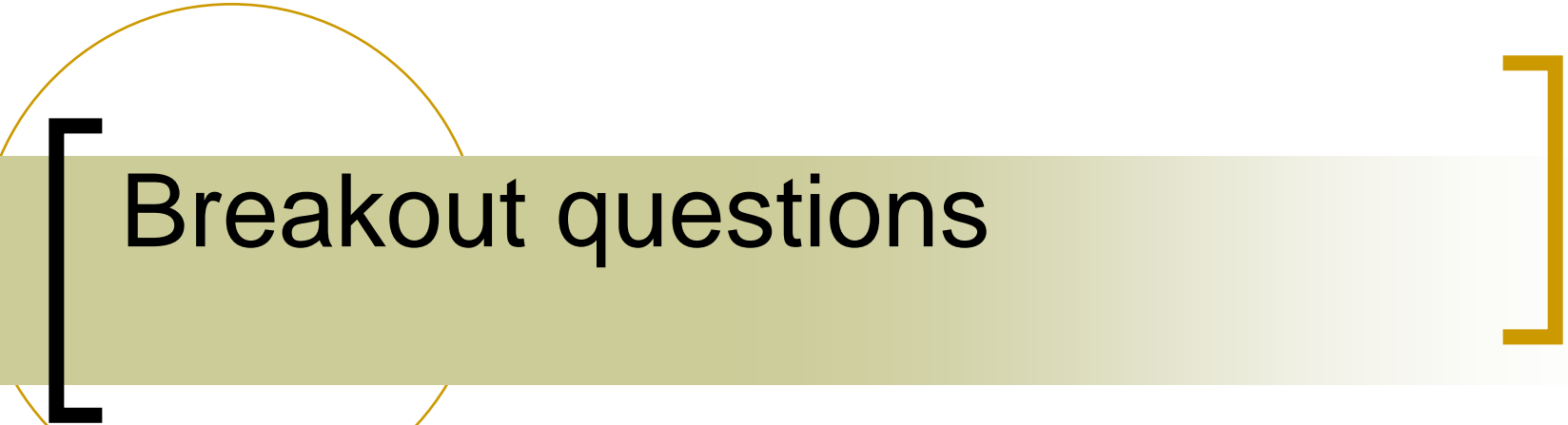


# Breakout questions

How can PMDSE data generated by the research network be used to strengthen decision making practices in drug safety and effectiveness in a (1) regulatory context and (2) Drug plan management context?

## Regulatory context:

- 1) What is the best mix of safety and effectiveness data (appropriate balance) to strengthen the drug regulatory decision making practice?
- 2) What level of value added is there to look at safety & effectiveness data for sub-groups of the population who are at risk of adverse effects or any other health product related problem?



# Breakout questions

How can PMDSE data generated by the research network be used to strengthen decision making practices in drug safety and effectiveness in a (1) regulatory context and (2) Drug plan management context?

## Drug plan management context:

- 1) What are the obstacles (barriers) from a practical perspective to using evidence on drug safety and effectiveness in drug plan management after drugs are approved for market?
- 2) How can these obstacles be overcome?