



Group exercise 1.2: Practical exercises of basic PV understanding (real life examples)

All participants
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Example 1

- Your colleagues from your clinical department tell you that they have outsourced the clinical activities for a phase III to a CRO. They will meet with the CRO tomorrow in Shanghai.
- Should PV also be at the meeting?
- If yes, what will you ask the CRO?

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Example 2

- You learn by chance that the manufacturing process is going to be changed for one of your old vaccines.
- Does this have any implication for PV?
- If yes, how will PV play a role in this process change?

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Example 3

- You receive a call from Chinese CDC that they have discovered that your hepatitis B vaccine causes narcolepsy in China.
- What steps will you take (or not take)?

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