Defining COUs
(without tears)

Klaus Romero MD MS FCP
Chief Science Officer, C-Path
What’s the point

• Unadopted solutions are not solutions

• The adoption of actionable solution requires adequate confidence from the relevant components of the ecosystem.

• Scientific solidity is necessary, but not sufficient, without a level of confidence “stamp”

• In practical terms, the name of of “stamp” is not as critical, as long as the “stamp” comes from the right place
What’s the main construct

- Actionable solutions need to have a defined intended application.
- If the intended application gets “formalized” in regulatory terms, it becomes a context of use (COU) statement.
- A well-defined COU becomes a useful compass to guide everything.
So...

- The COU needs to consider the question(s) that need(s) to be answered at a specific stage of drug development.

- The COU serves as a compass for the evidentiary considerations.

- If the evidence so requires, the COU should be adaptable, as long as the answer it provides is still relevant for drug development.

c-path.org