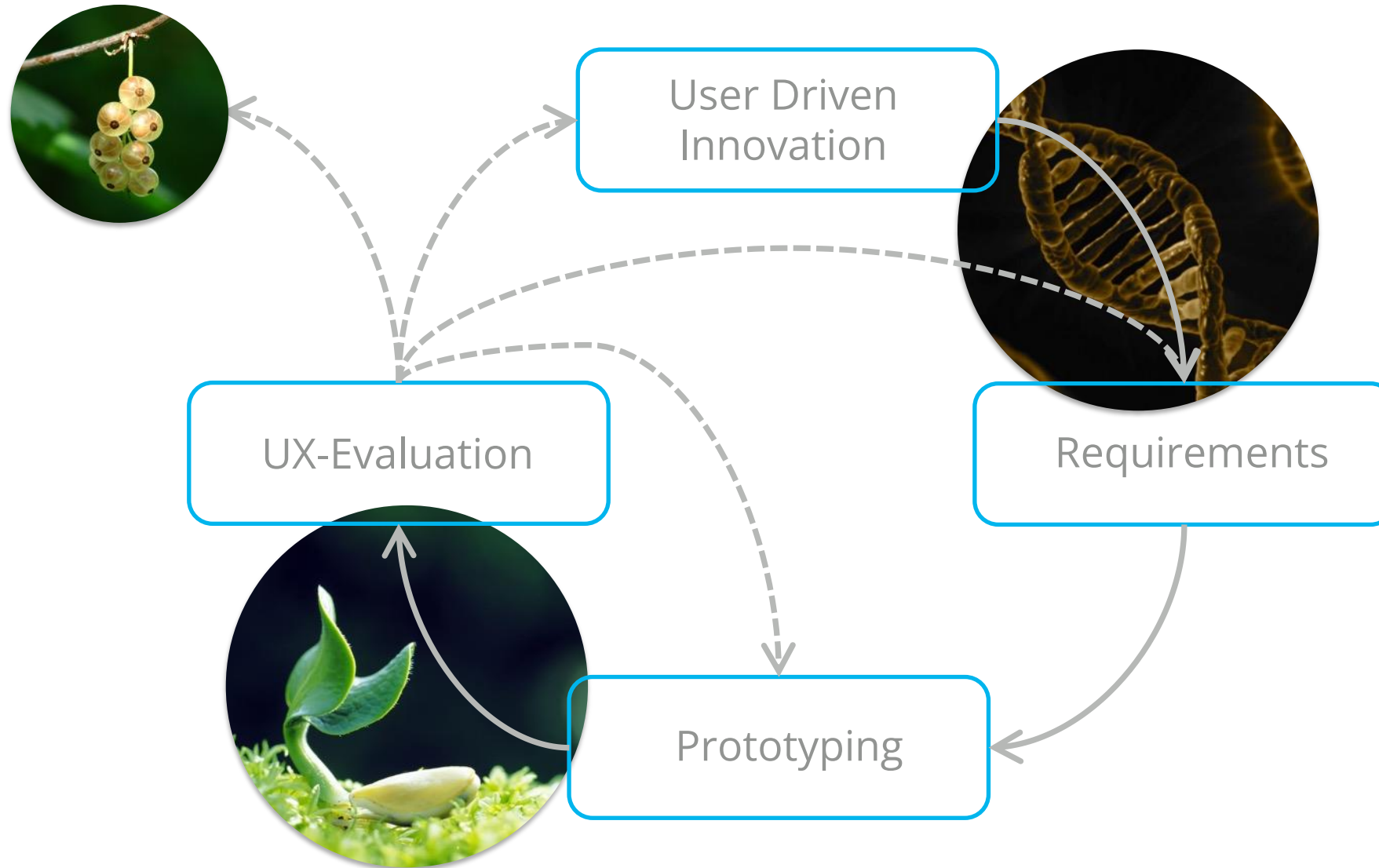


Usability Engineering und Risikomanagement – ein Staffellauf

LISAvienna Regulatory Konferenz für Medizinprodukte und In-vitro Diagnostika 2023

17.10.2023

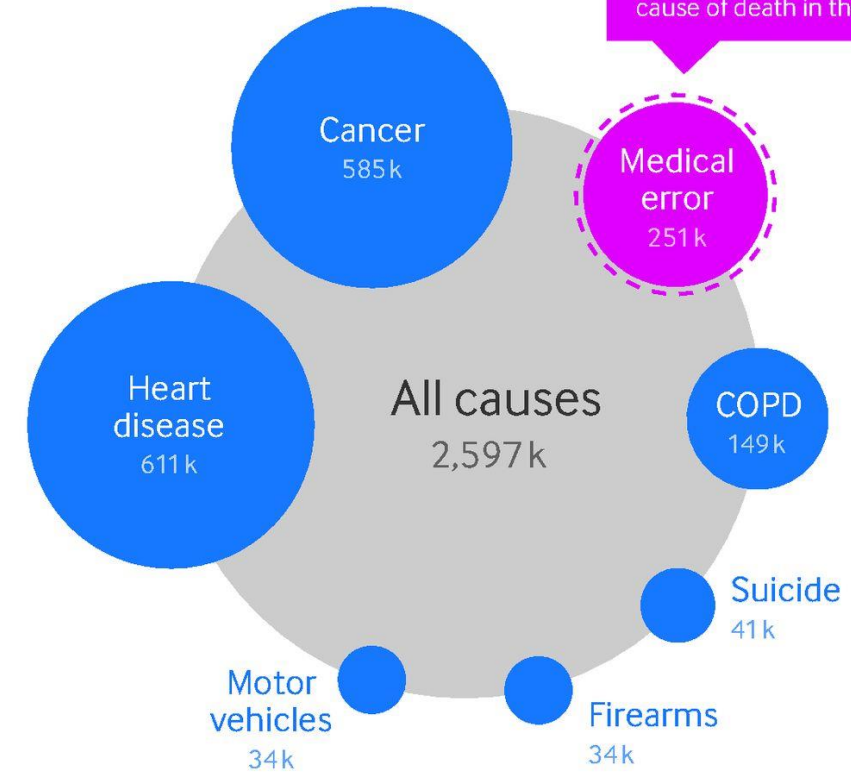
Potentials of Usability Engineering



Medical Error Problem ties Usability to Risk

1. Focus: product development.
2. Usability engineering as an important tool to make medical devices safer.
3. Harm is a problem in the design of a system, not an error by individual users.
4. Focus on identifying and controlling errors in the design of user interfaces that could lead to damage or compromise medical care.

Causes of death, US, 2013



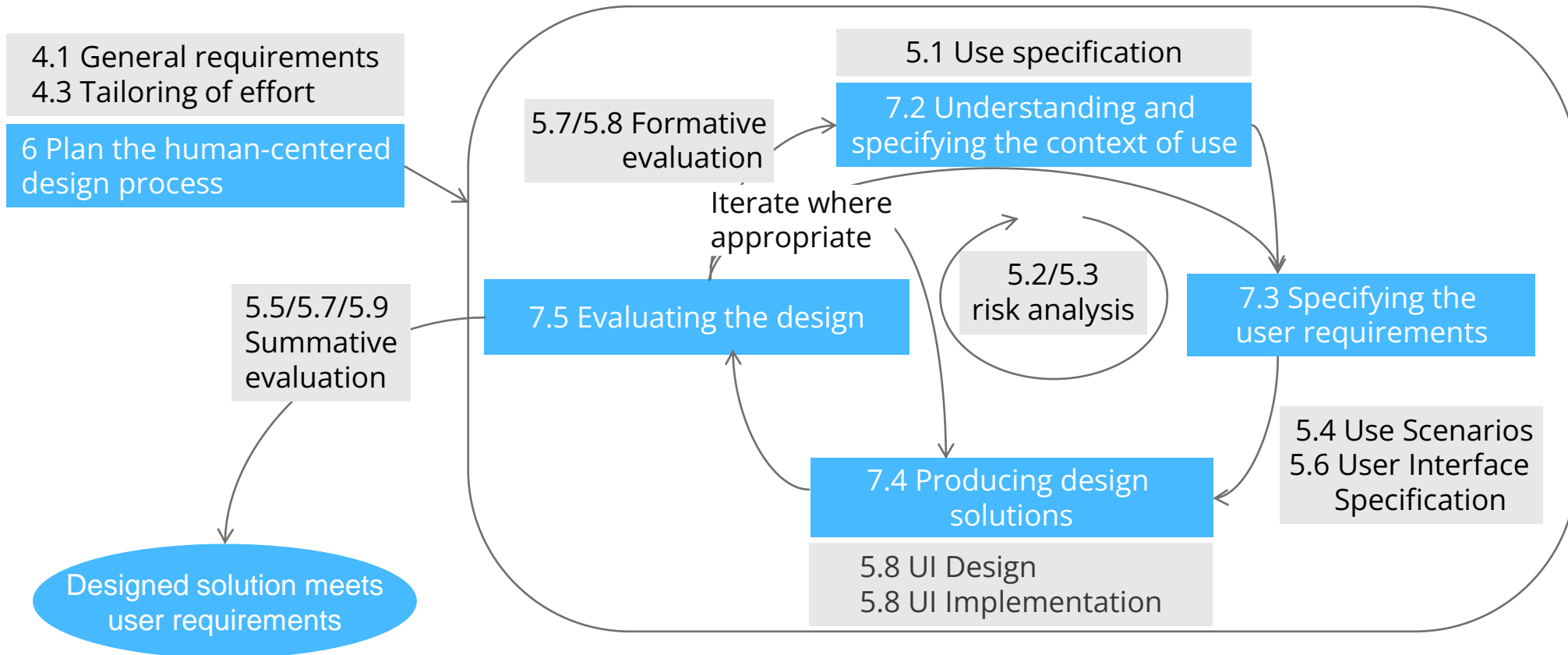
Based on our estimate, medical error is the 3rd most common cause of death in the US

However, we're not even counting this - medical error is not recorded on US death certificates

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Data source:
http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf

Usability Engineering Process



ISO 9241-210:2019: Human-centred design process for interactive systems

ISO 9241-210:2020

IEC 62366-1:2015

Boxes

USABILITY ENGINEERING



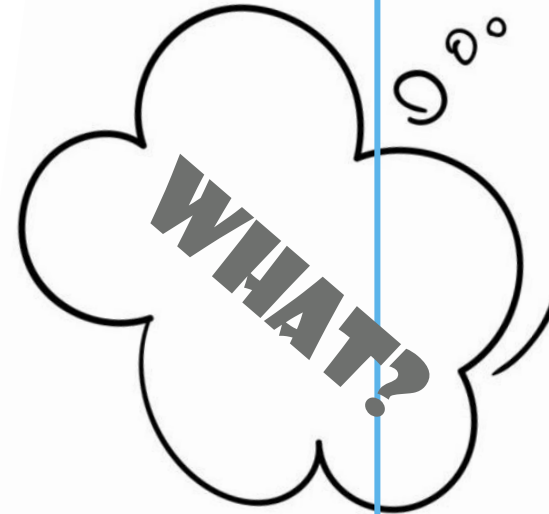
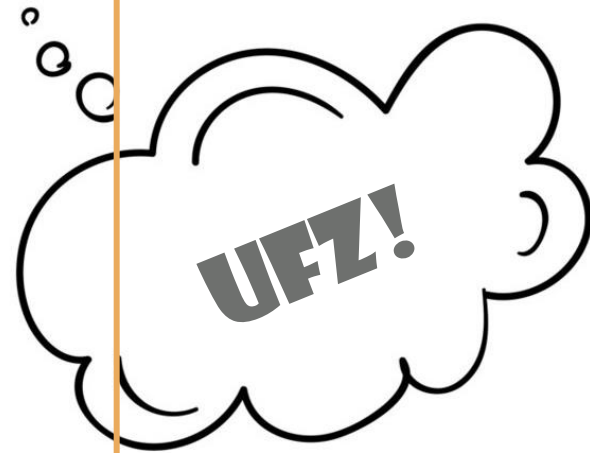
NEUTRAL ZONE



RISK MANAGEMENT



Think out of the Box?



Learning with each other?



**YES I CAN -
I TOOK A
SEMINAR!**



Be open minded?



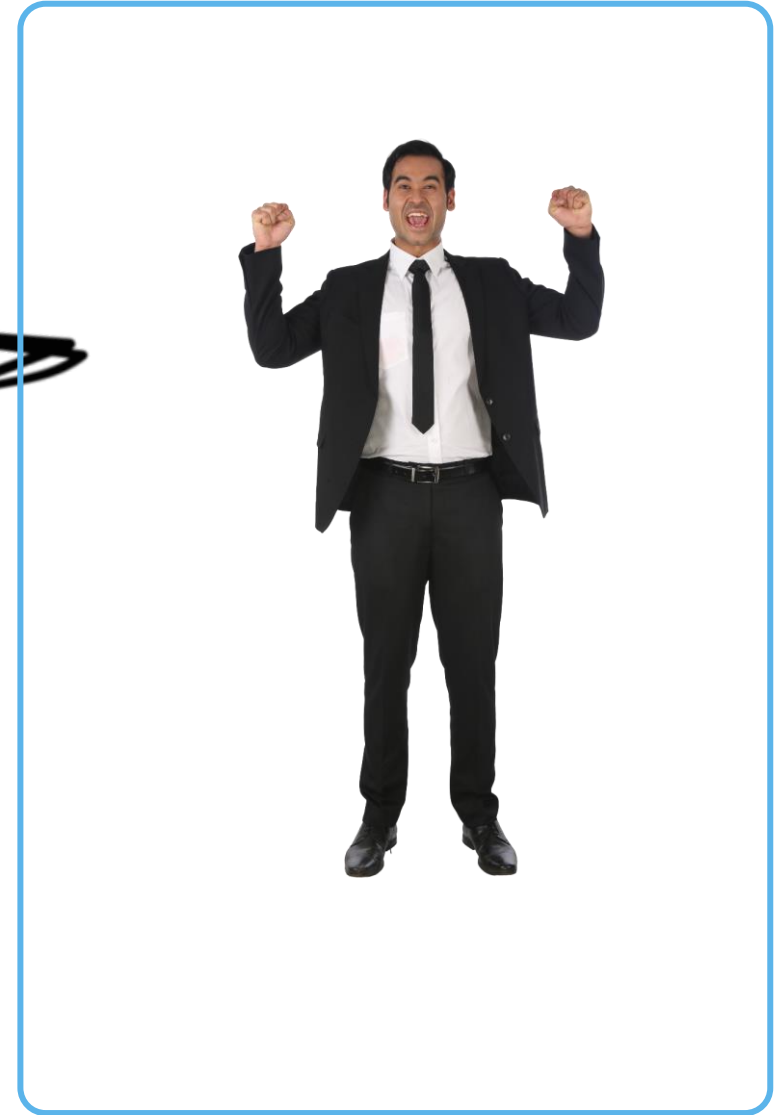
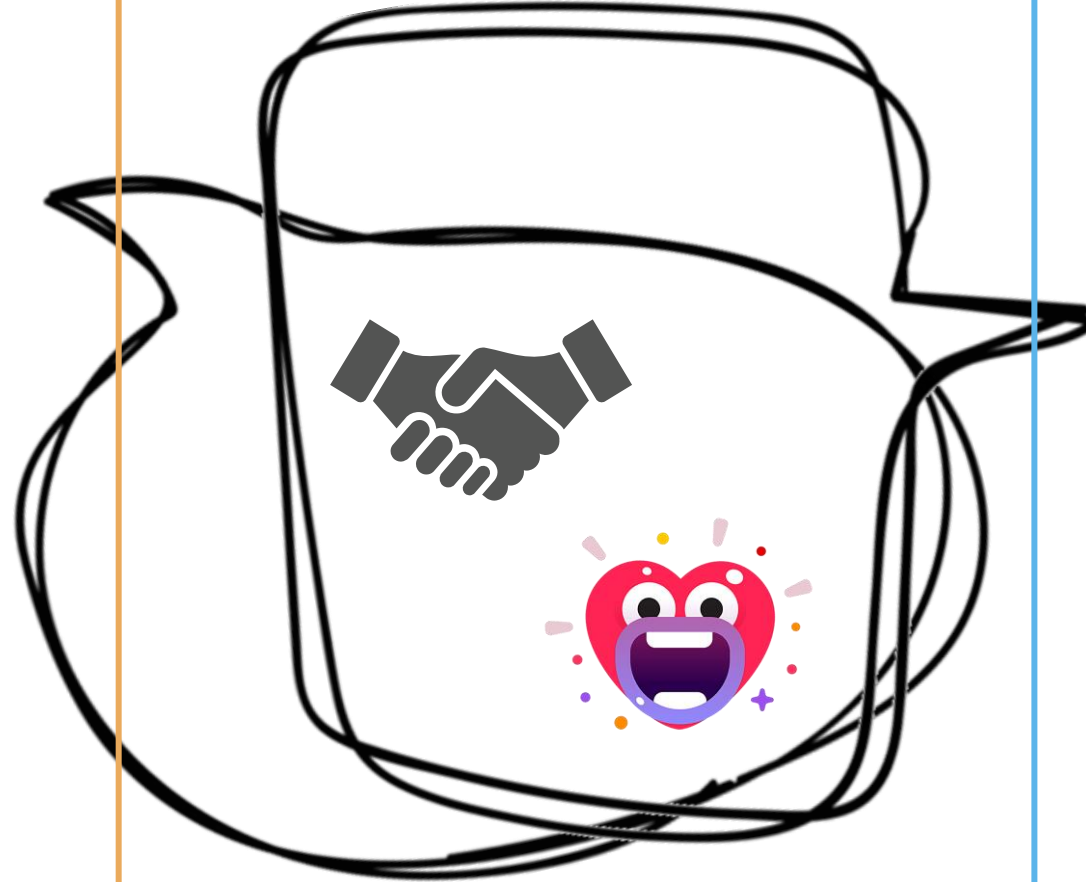
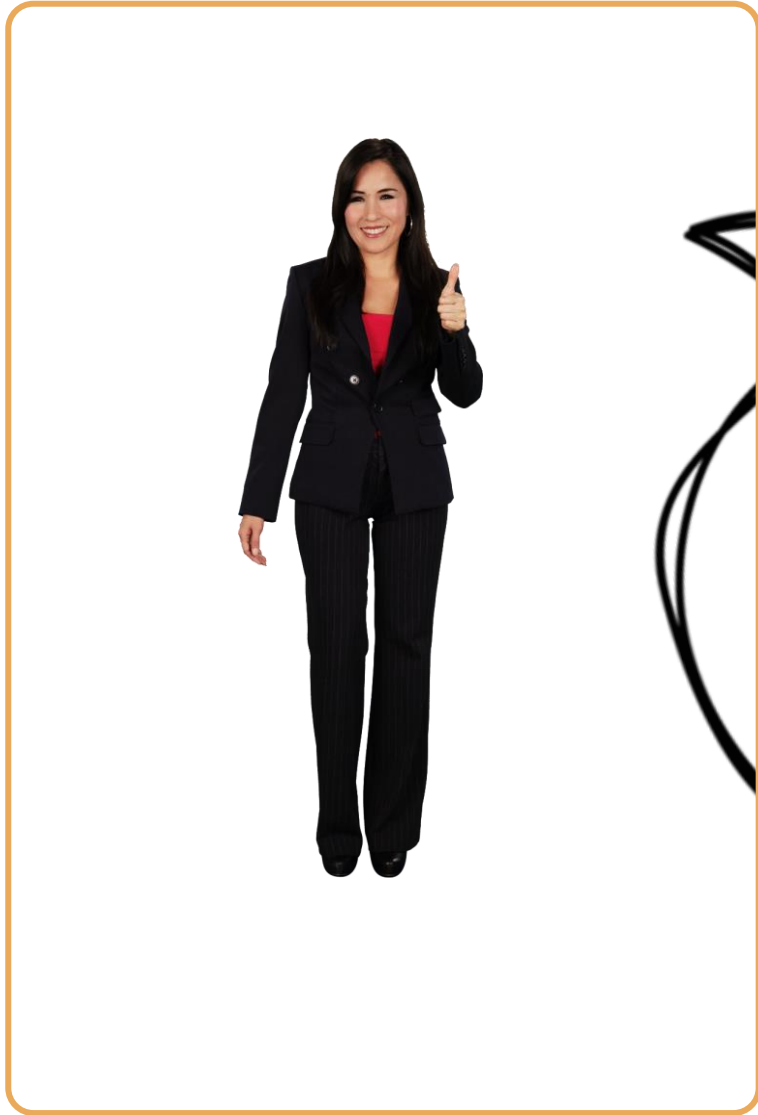
**I CAN HELP
WITH USE
RELATED
RISKS!**

**YOU WANT
MY JOB!**

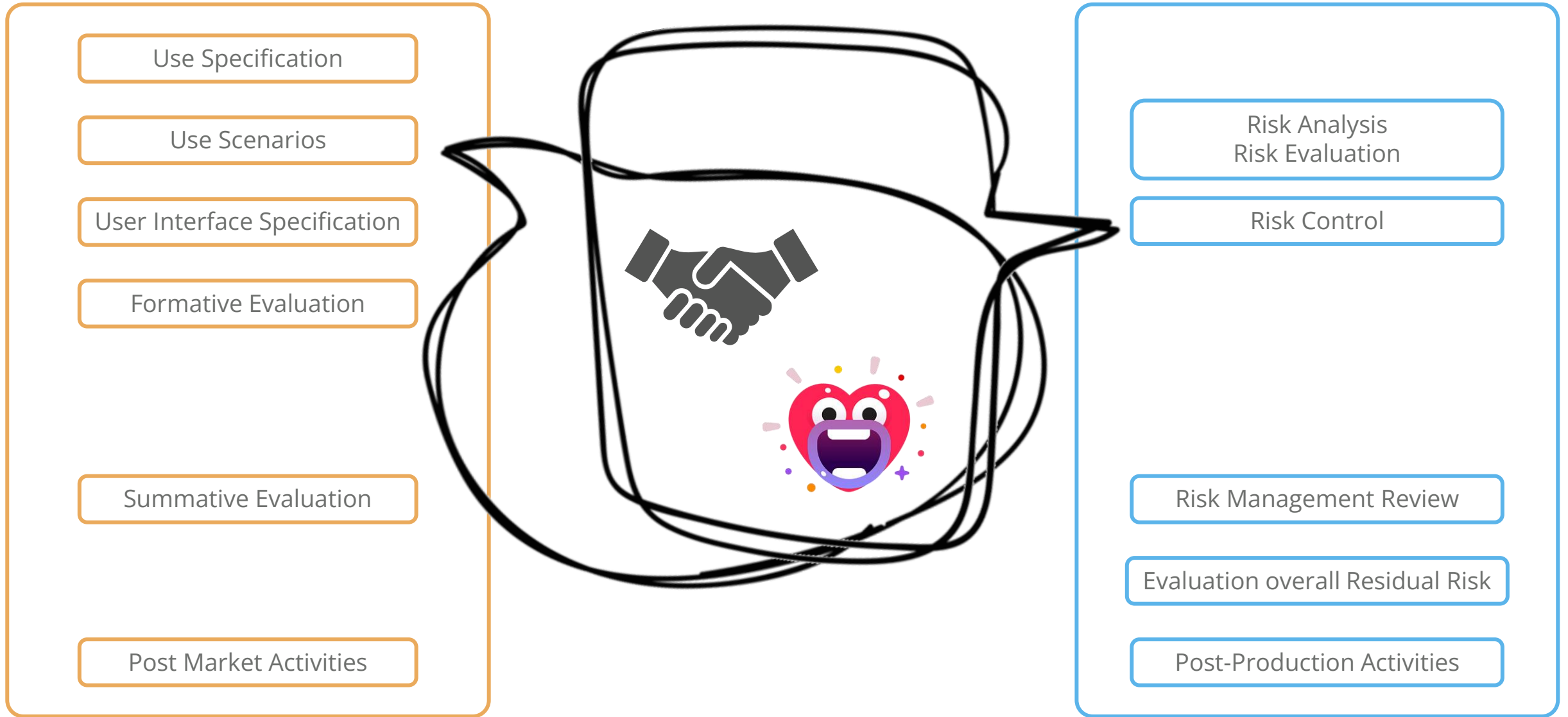
**GET OUT OF
MY SPACE!**



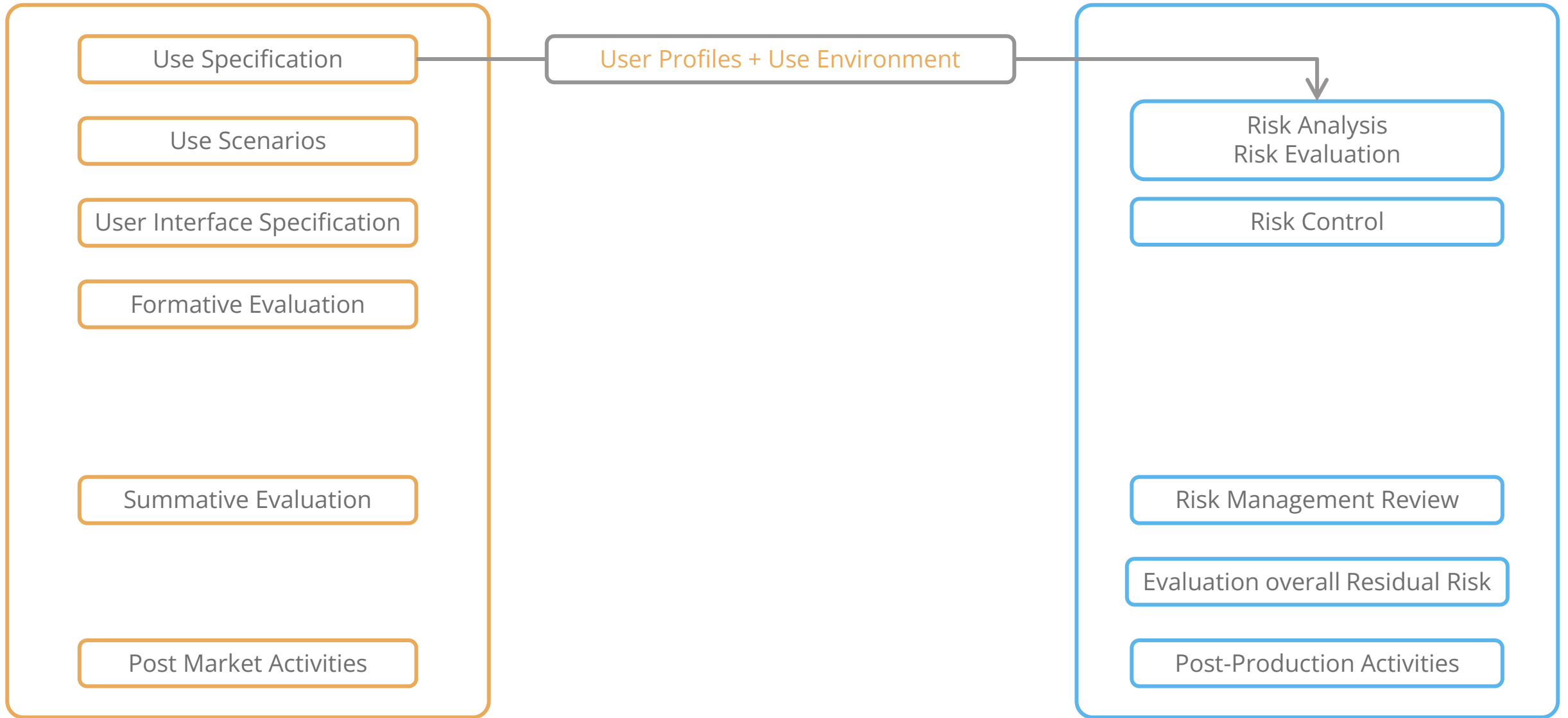
Fill the Space between the Boxes!



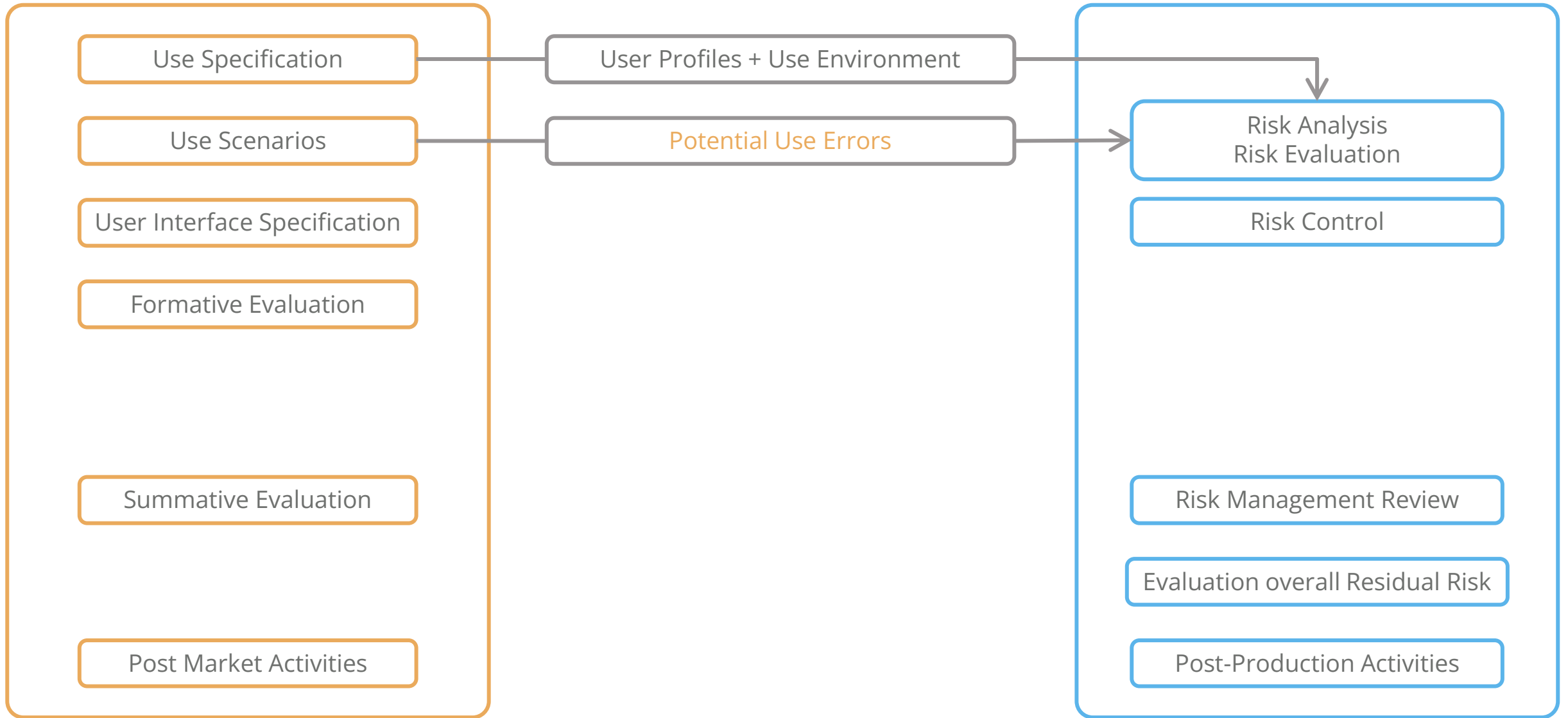
Given structures.



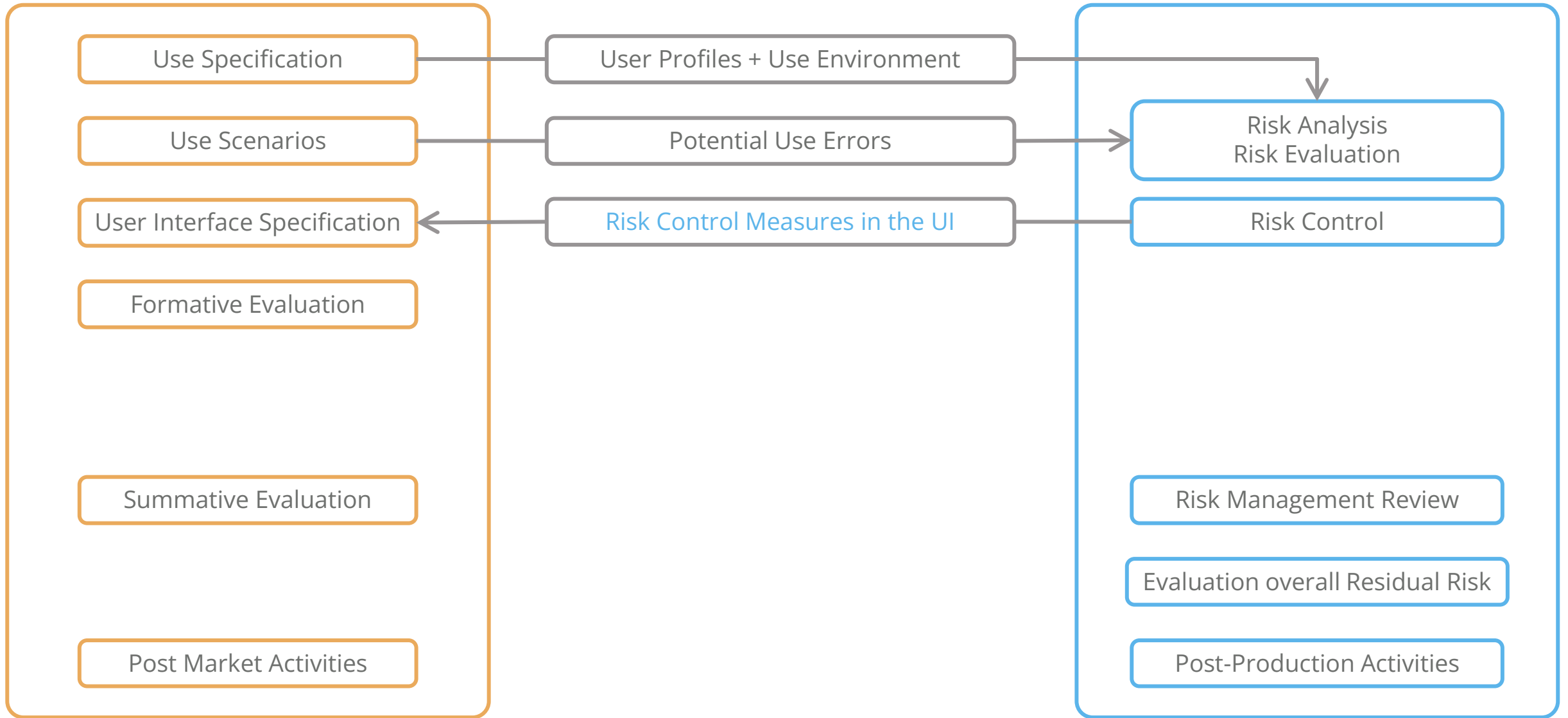
It's a decision not a description!



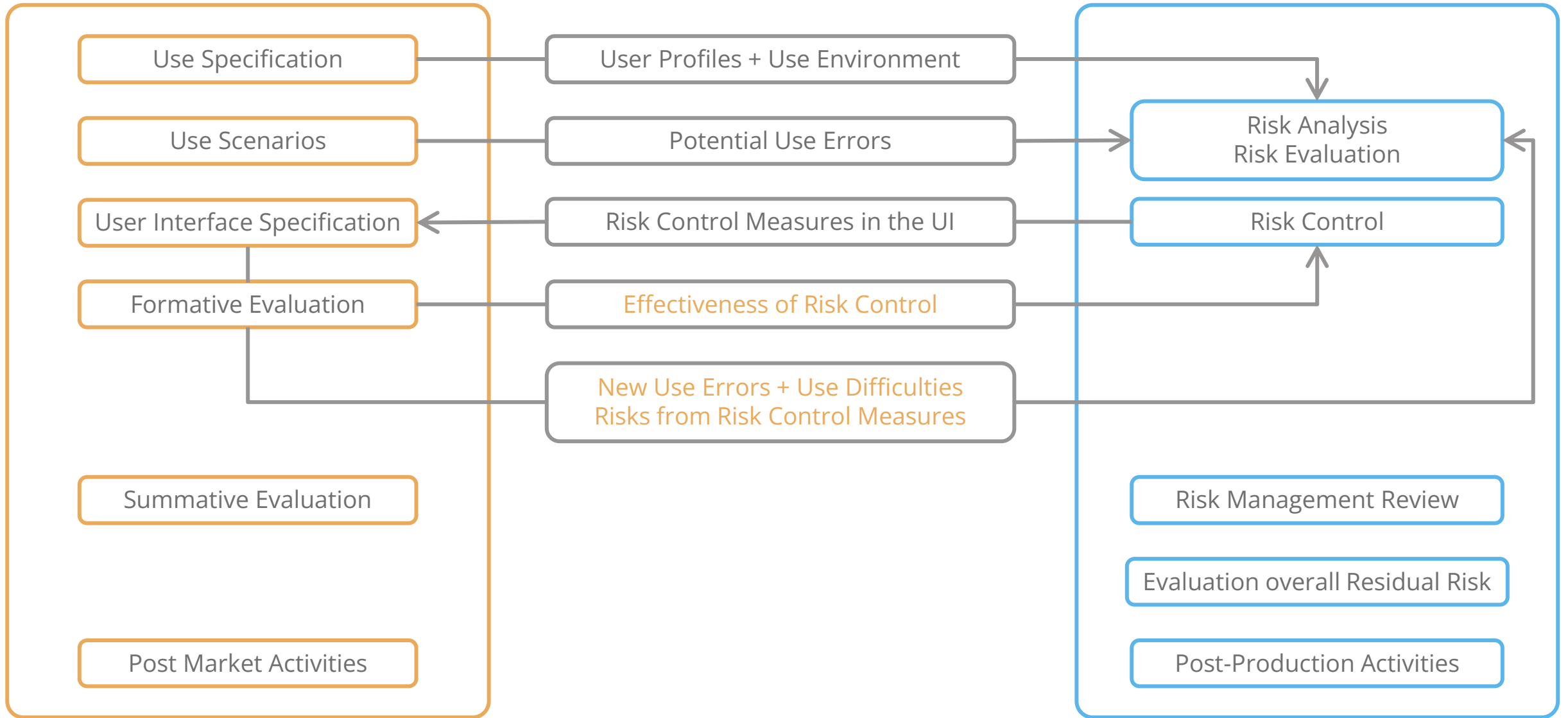
Correct Use and Use Errors – nothing more!



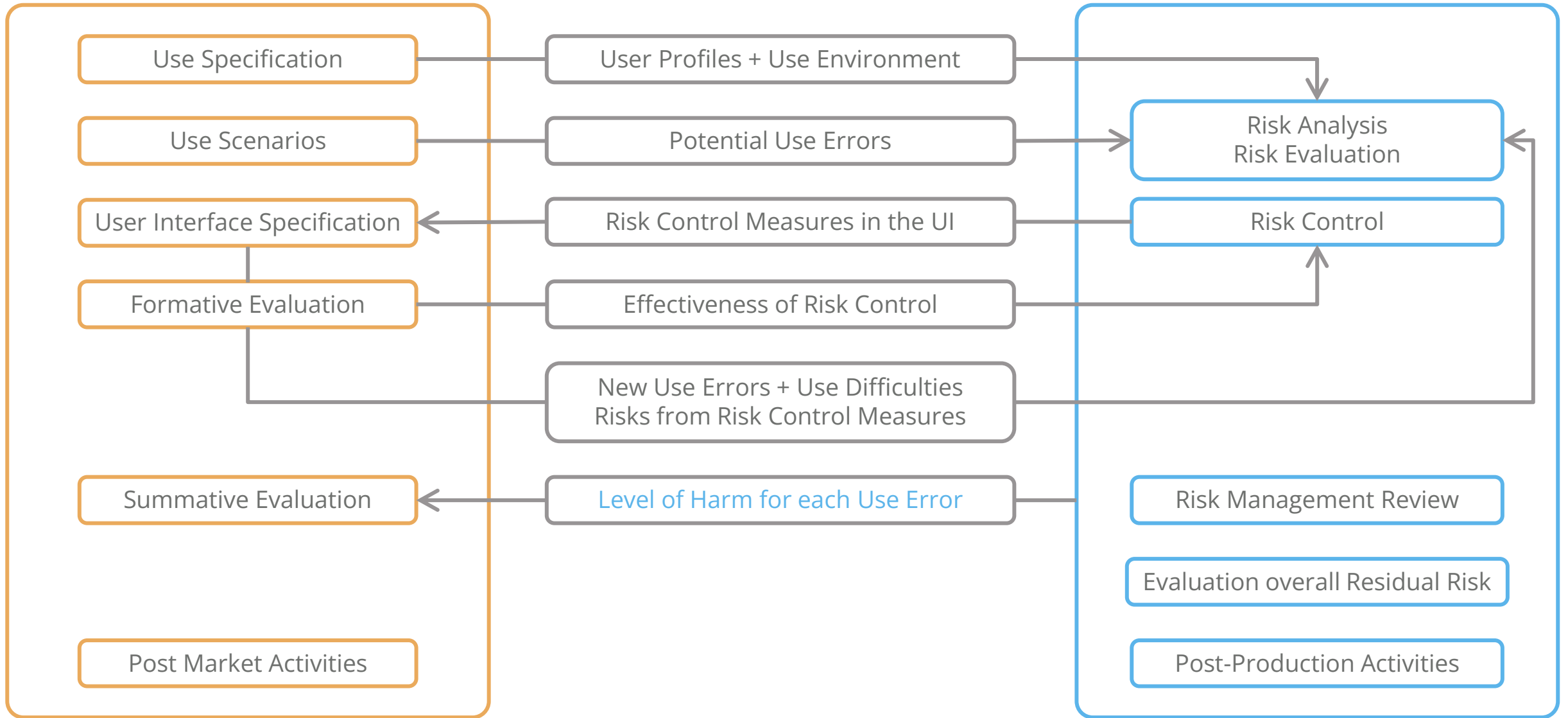
Risk control in the User Interface = User Interface Specification of IEC 62366-1



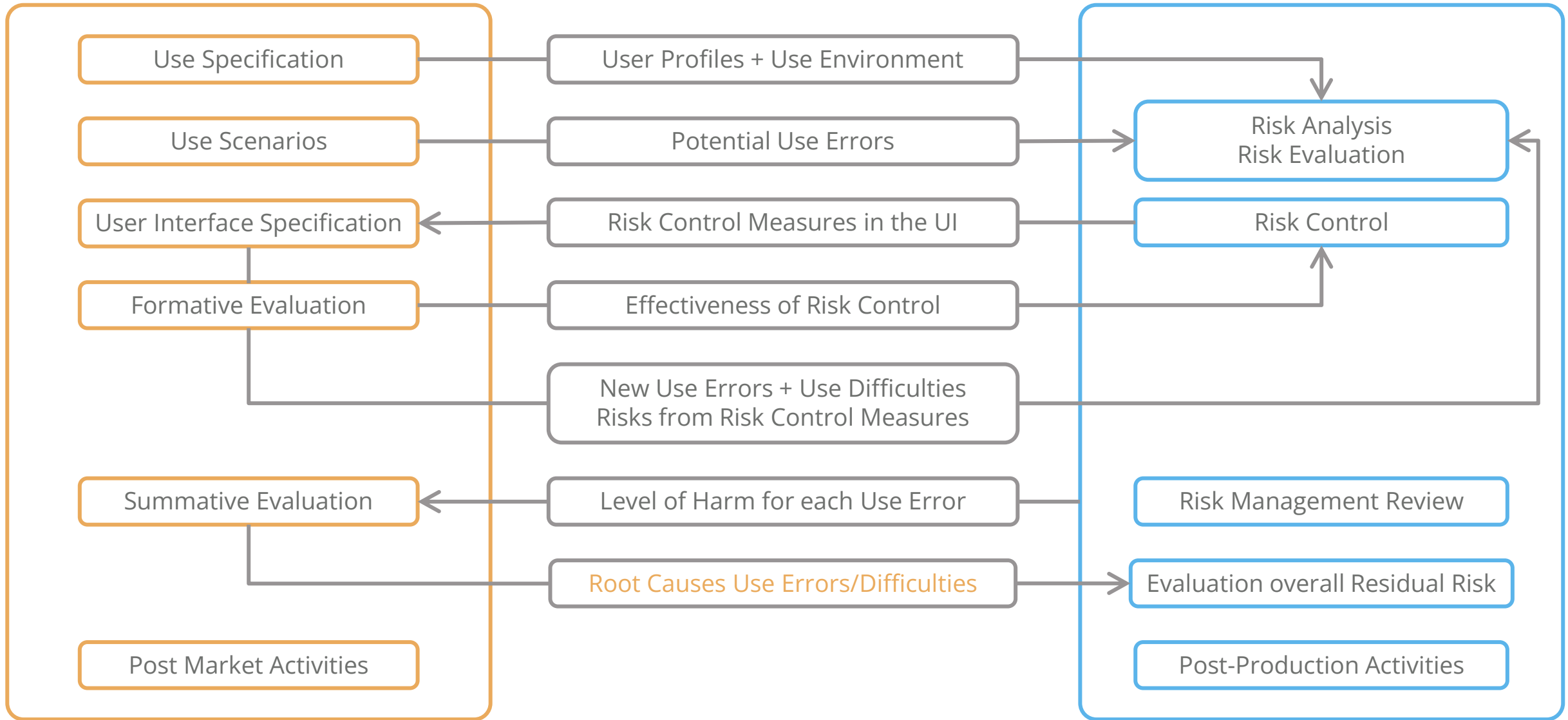
What it is all about!



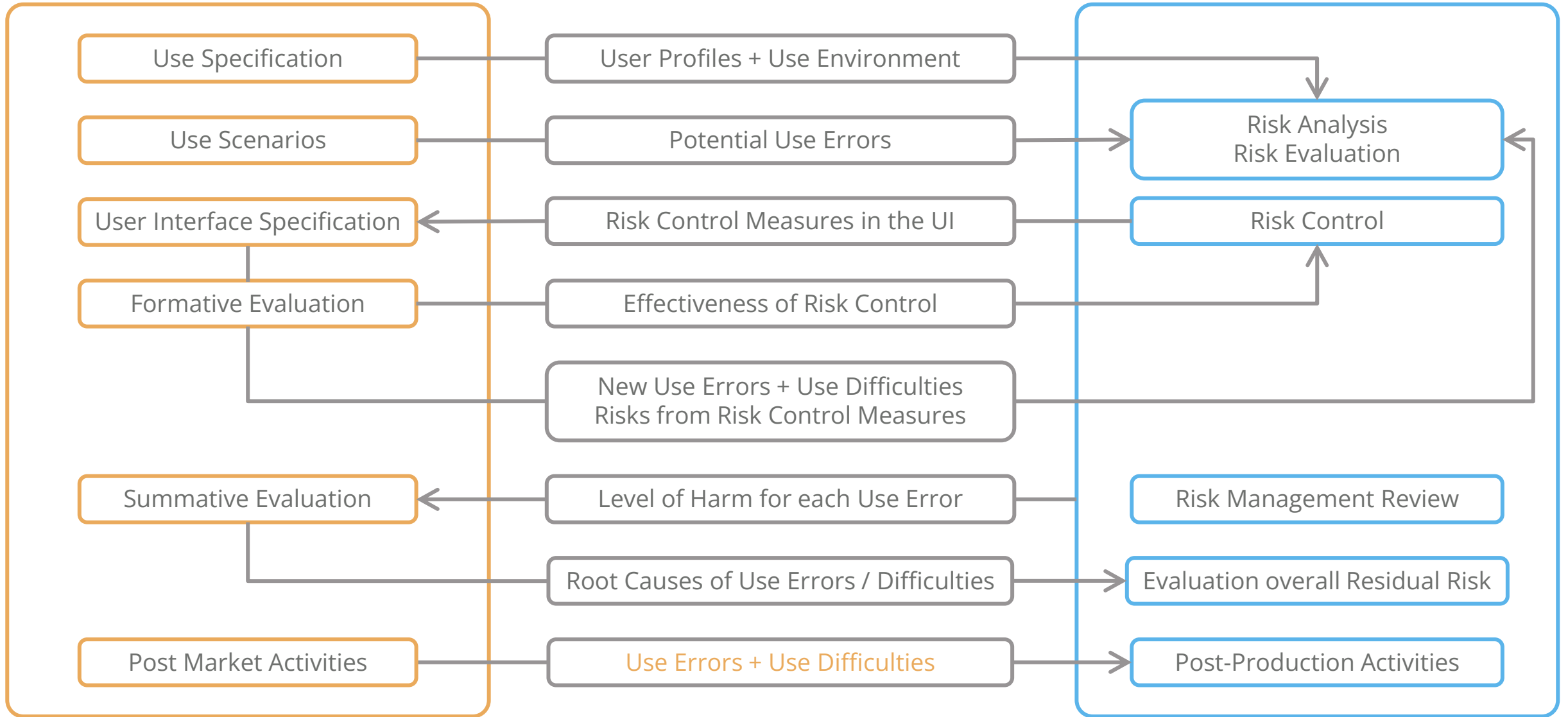
Hazard related Use Scenarios and Critical Tasks



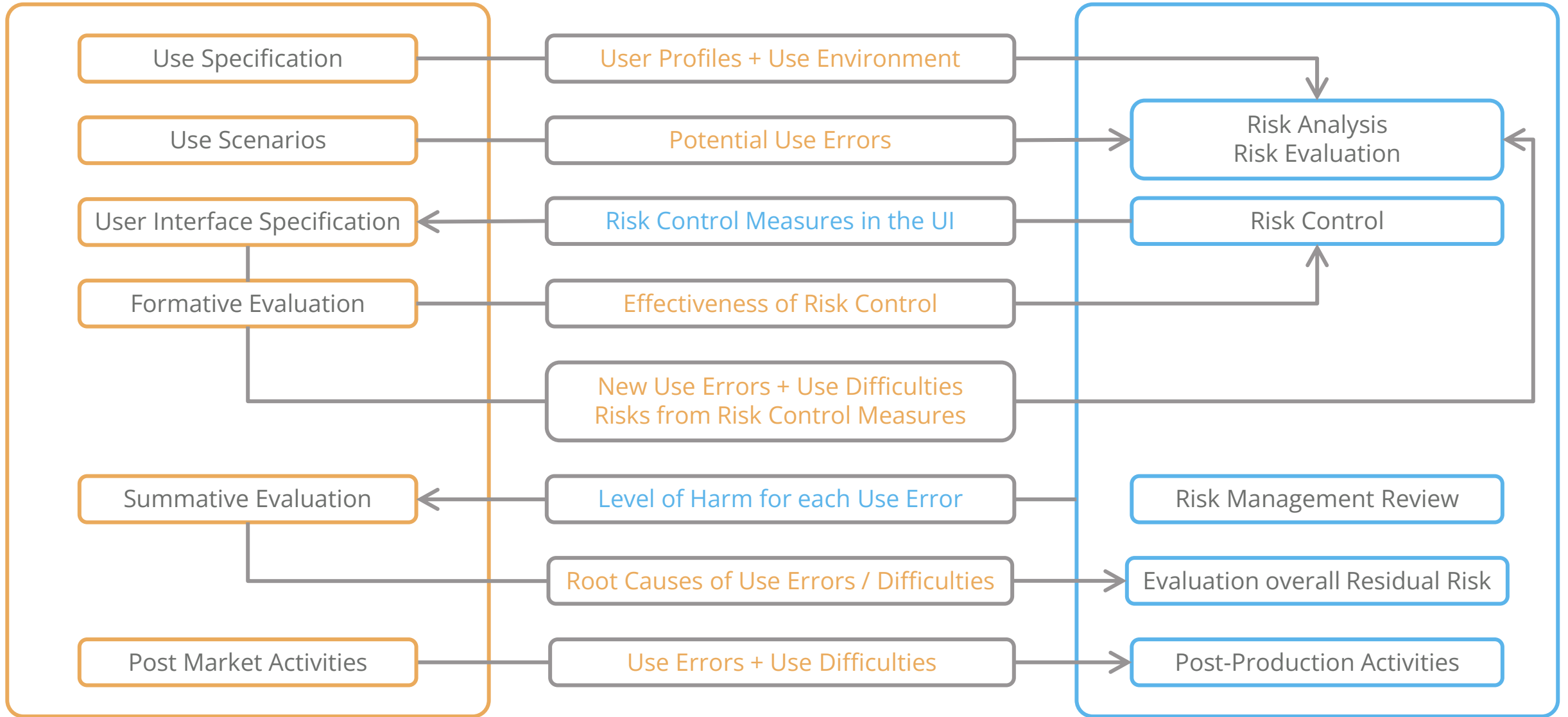
Again: Stop Usability before it gets risky!



Post Market Activities



The Team Relay



Contact



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