

The Risk-Tier Pyramid

Every program has more risks than time.
A shared scoring method shows where to act first.

$$\text{Impact} \times \text{Probability} \times \text{Urgency} \times \text{Dependency} = \text{Risk Tier}$$

? Impact:

How much damage would it do:
a clinical hold, a delay, a cost overrun?

? Probability:

How likely is it to happen if
nothing changes?

? Urgency:

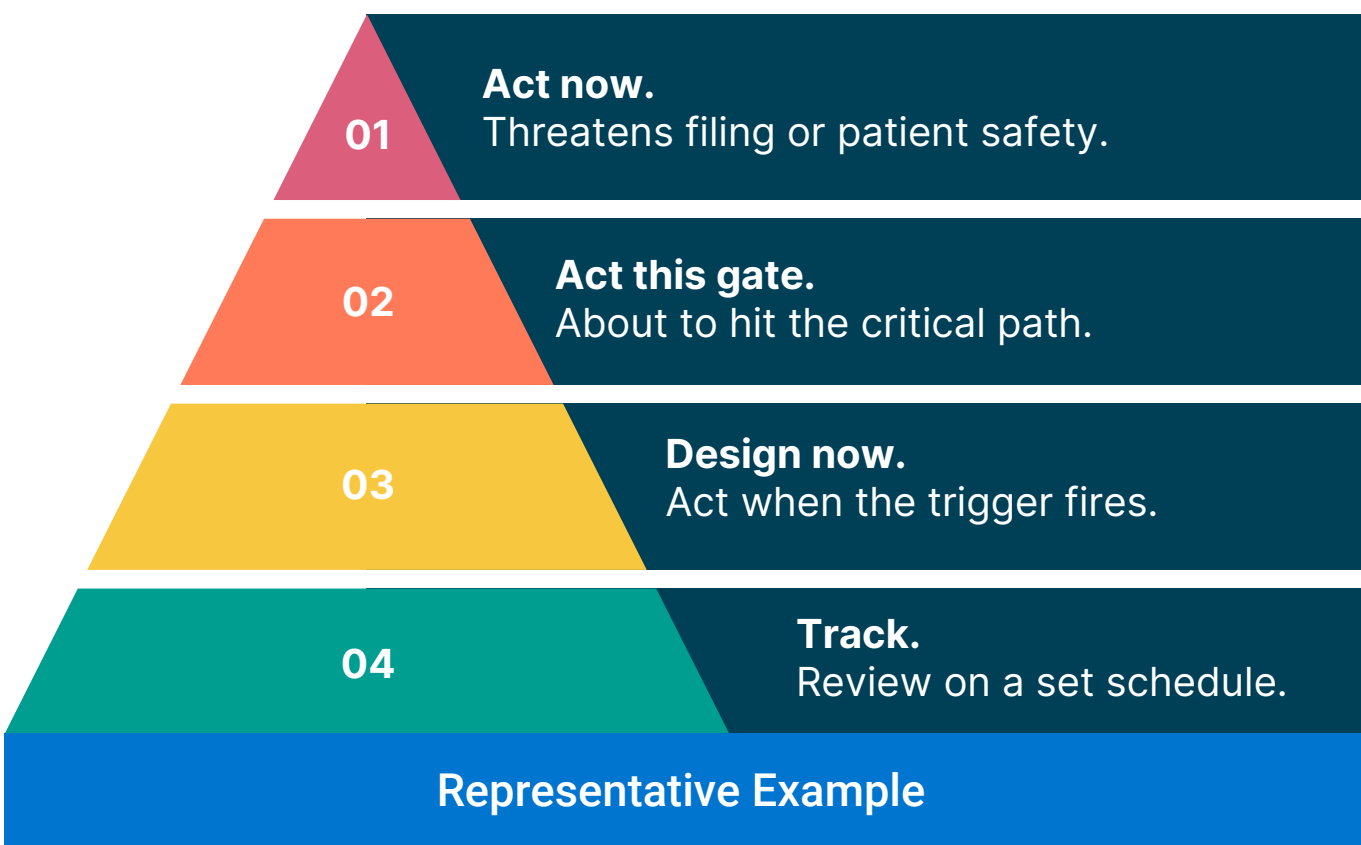
How soon will your options close?

? Dependency:

How many other functions and
decisions rely on it?

Dependency is the factor most risk registers miss.

A risk that touches CMC, nonclinical, and clinical at once can outrank a bigger risk that stays inside one function.



01 The material tested in tox differs from the clinical material, with no bridging argument. FDA's guidance asks for this disclosure by name.

01 Long-lead tox studies needed for a longer Phase 2 haven't started. Each takes 6–12 months, and the clock is already running.

01 CDMO agreements don't include QP release provisions. Not urgent for a US-only trial, but expensive to reopen if Europe enters the plan.

01 A vendor's single, closed inspection observation that doesn't recur or touch your unit operations.

Risks Move Between Tiers

A Yellow risk left alone doesn't stay Yellow. As gates pass and options close, urgency rises and risks climb the pyramid. Re-score at every gate, not just once before filing.



How Syner-G Helps

Syner-G's integrated CMC360 model scores risk across functions, not inside them, so your team spends its time on the risks that actually set your timeline.

Find your Red risks before FDA does. Connect with our team.