

# From Compliance to Confidence





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## Purpose of Today



## Agenda

1. The Post-Go-Live Reality
2. Common Adoption Barriers
3. Breaking the Barriers

# The Post-Go-Live Reality



# What we aim to achieve with the Go-Live

Confident eTMF ops



## Control

One place to manage eTMF documentation, workflows, and storage.



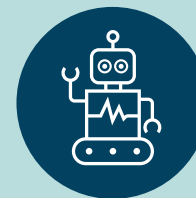
## Consistency

Teams, sites, and countries filing against the same model, with same expectations.



## Inspection Readiness

Our TMF is not assembled under pressure before an inspection.



**Ready for AI  
enabled ways of  
working (?)**

# And yet, a few months later...



- 1** I'm not sure where this document belongs — or which template to use

Users are hesitating because it's not clear.



- 2** This feels harder than before. I'll just do it my own way

Users are pushing back because it's slowing them down.



- 3** The dashboard says 95% complete. I don't trust it. I'll rely on my Excel tracker

Users don't trust the numbers, so they revert to familiar tools.



- 4** I don't trust the recommendations coming out of these AI POCs

Users don't trust the output, so they won't use it.



Meeting the intended objectives is not easy.

According to Gartner, **48%** of digital initiatives fail to meet their original business targets (*Gartner 2026*).

An iceberg floating in a dark, choppy sea under a cloudy sky. The visible tip of the iceberg is small and jagged, while the vast, dark, and textured mass of the iceberg is submerged beneath the water's surface. The horizon line is visible in the distance.

# The problem was never mainly technological

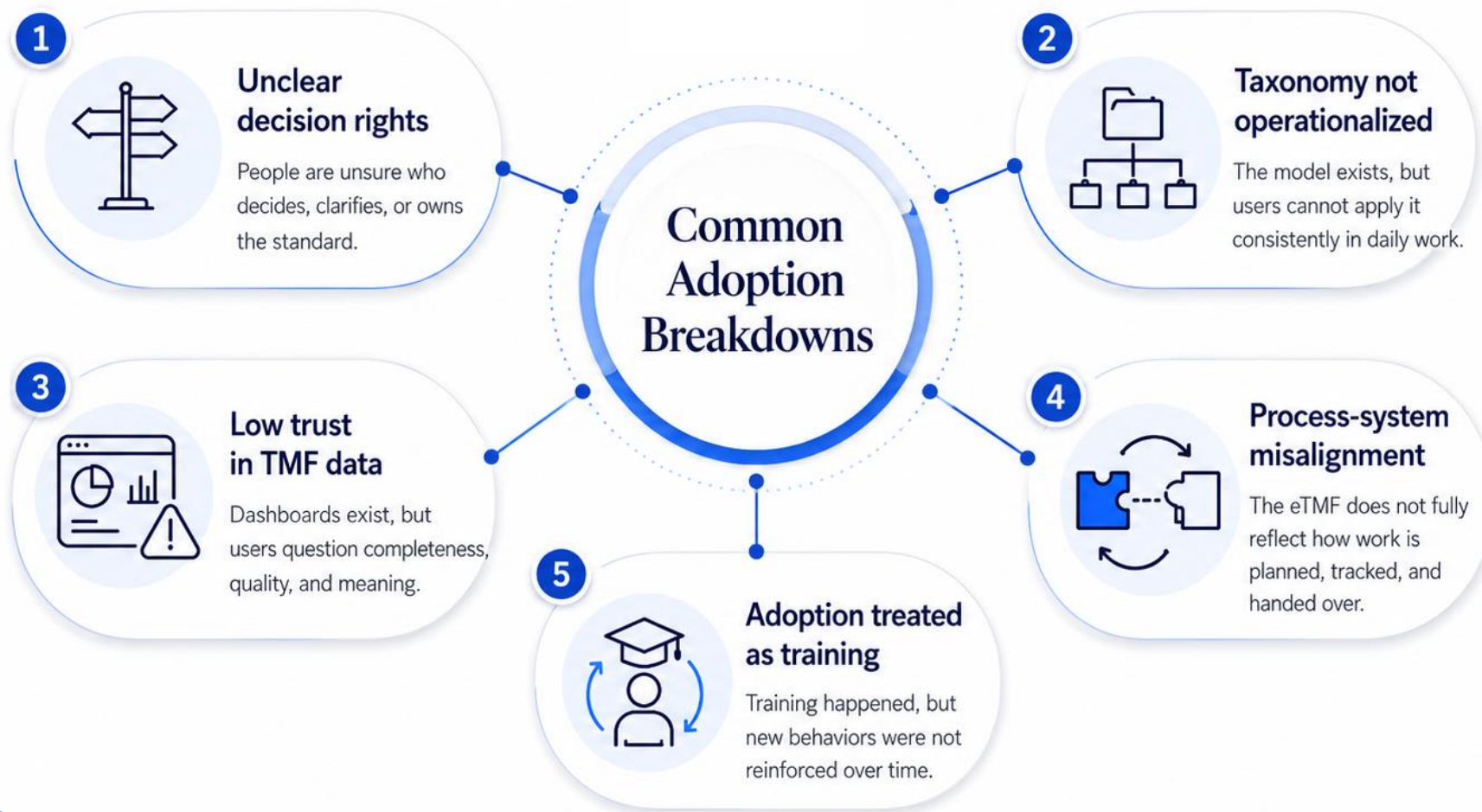
What looked like a technology issue was often driven by what sat beneath the surface. Over time, small gaps compounded until adoption began to break down.



# Common Adoption Breakdowns



# Across the symptoms, there appear common adoption breakdowns

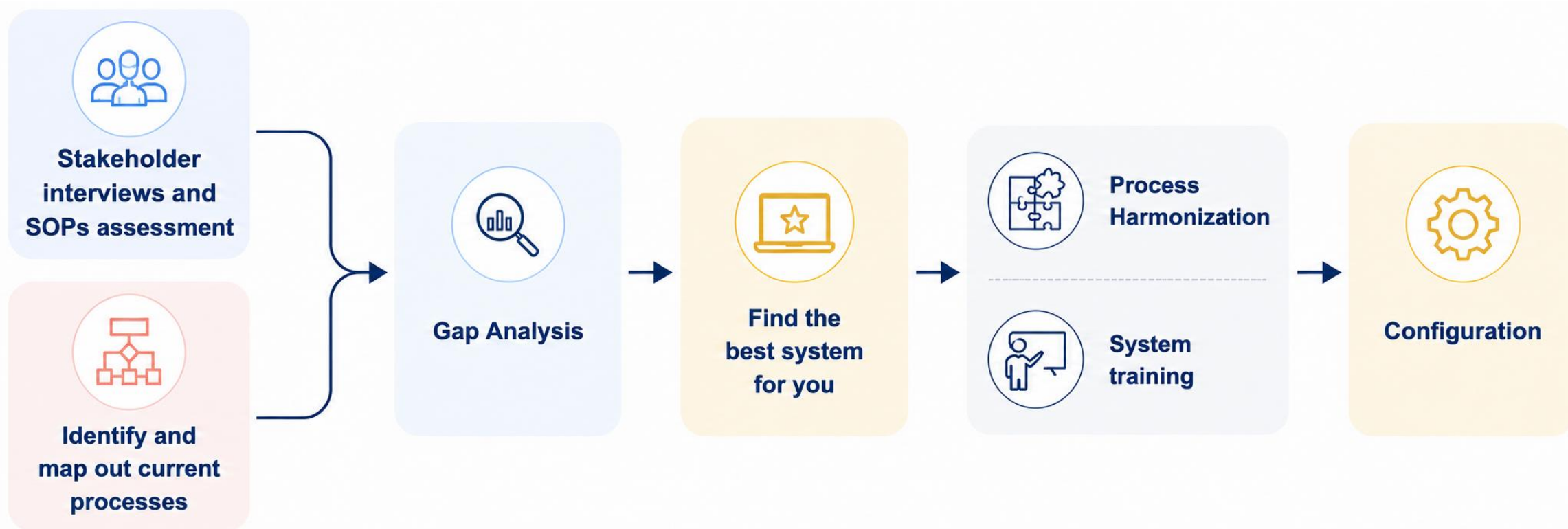




# Breaking the Barriers

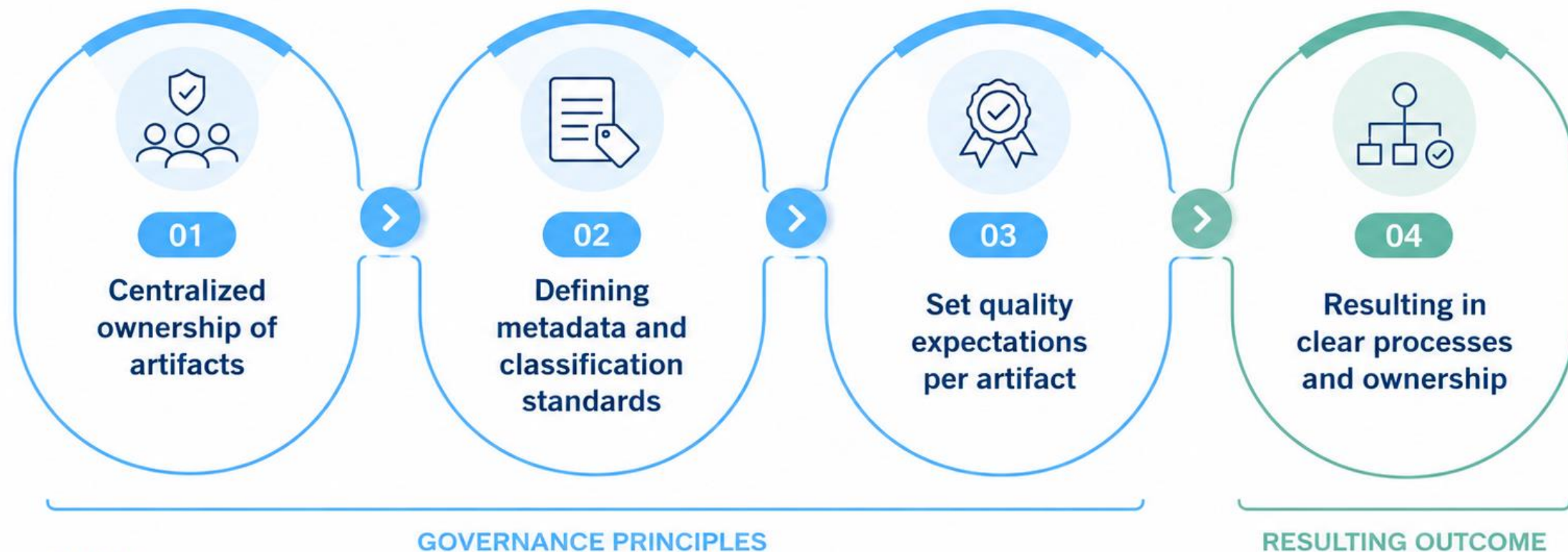


# Tailor the system to your processes - not the other way around





# Embed Data Governance Principles into your eTMF ops

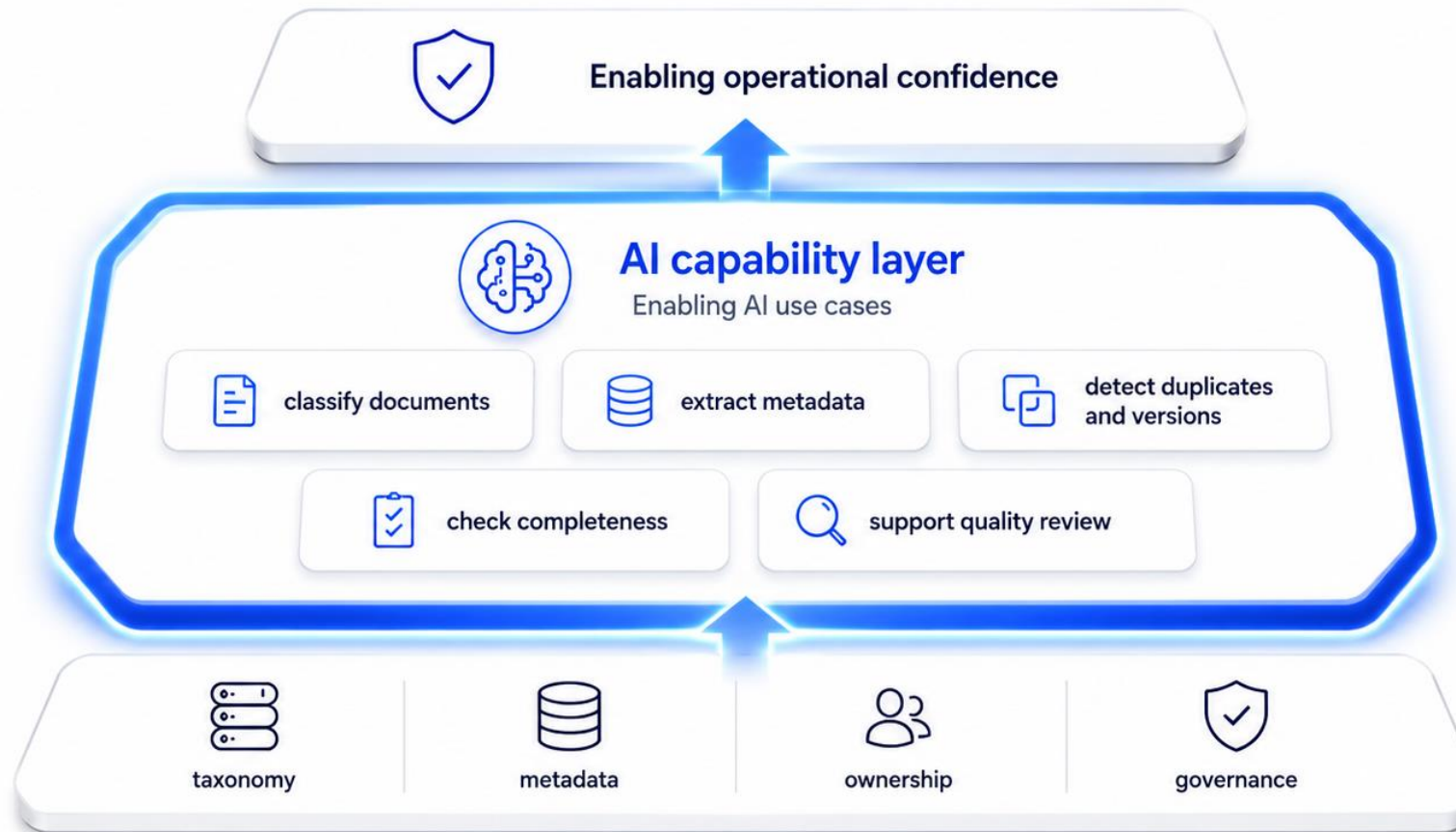


# OCM is not a Go-Live Activity



OCM continues after go-live — building confidence, driving adoption, and maximizing the value of your eTMF.

# AI will compound the foundation (good or bad)





# Thank you.

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