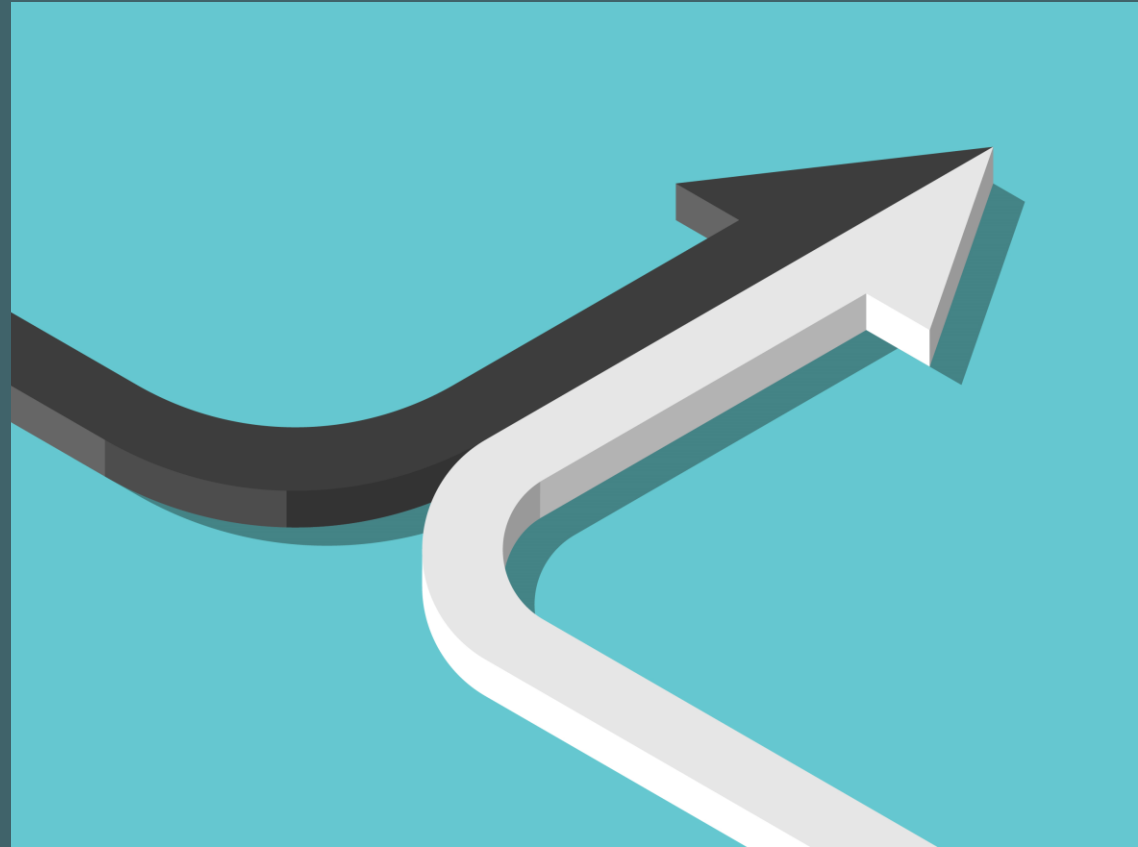


# Protect Your Trials During CRO Consolidations



Jesse C. Kooker, MPH  
Michael McLaughlin, MS, MSE, RAC

# Agenda

- Anticipated Risks During Selection
- Protection of Timelines & Deliverables
- Governance in an M&A Environment

# Anticipated Risks During Selection

- Expect that the CRO you contract with will go through some type of transformation
- Small/Mid-sized organizations often believe in the “Fit-For-Purpose” model
- Functions where you insist on continuity should be critically considered
- The systems & platforms used should factor in your selection criteria
- MSA should include language to insulate against organizational changes
- Insist on some level of governance

# Protection of Timelines & Deliverables

- If none already exists, establish relationship with new leadership
- Ask for a plan to ensure continuity, personnel and study management
- Leverage other relationships your organization may have
- Maintain your own set of study performance metrics
- Be indifferent to the woes of merger

# Governance in an M&A Environment

- Develop a structure that meets your need – don't accept a template
- Expect changes in leadership

# Summary

- Unless your organization is willing to insource all functional activities, M&A is a reality that all organizations will be forced to deal with
- Expectation is the key to mitigating risks
- Relationship management will be your best tool to ensuring your program's goals & objectives are maintained

# Thank You

Jesse Kooker

[jesse.kooker@dermavant.com](mailto:jesse.kooker@dermavant.com)

Michael McLaughlin

[m.t.mclaughlin@hotmail.com](mailto:m.t.mclaughlin@hotmail.com)