

Recognition & Collaboration: A Customer's Perspective

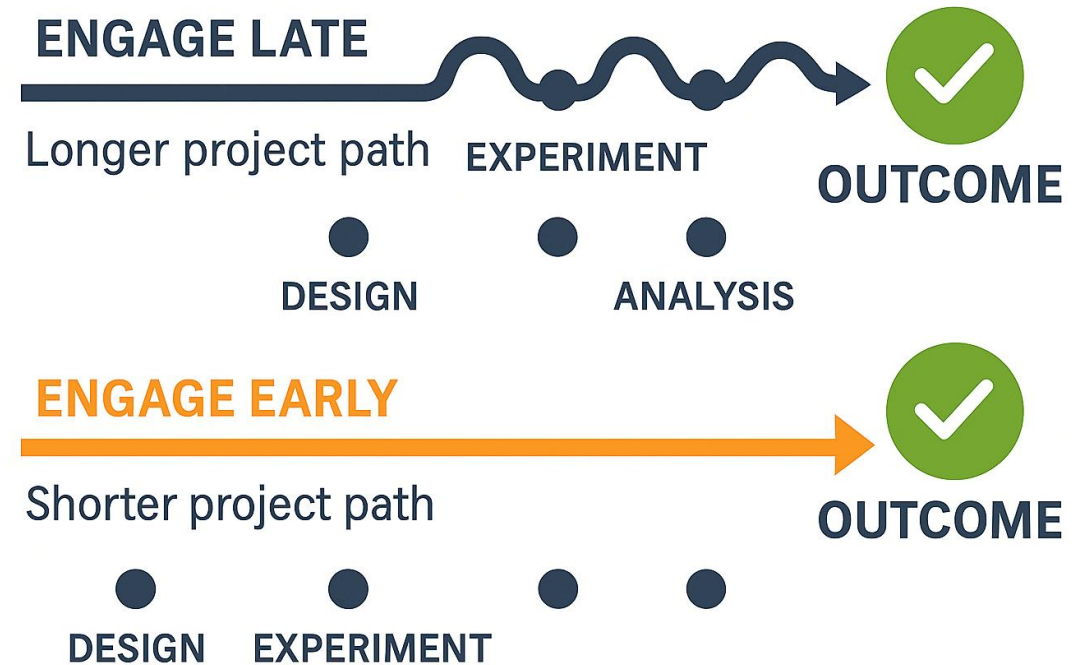
John Farris | Quality & Compliance Leader

Statisticians as strategic co-architects of outcomes

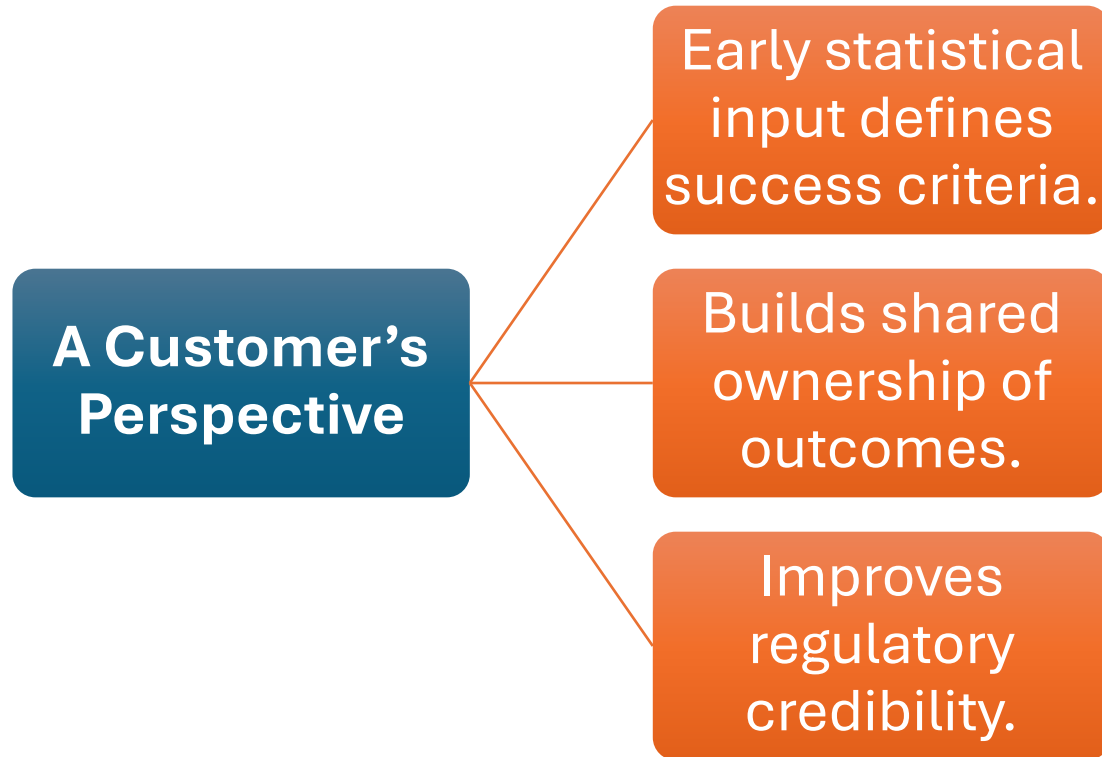
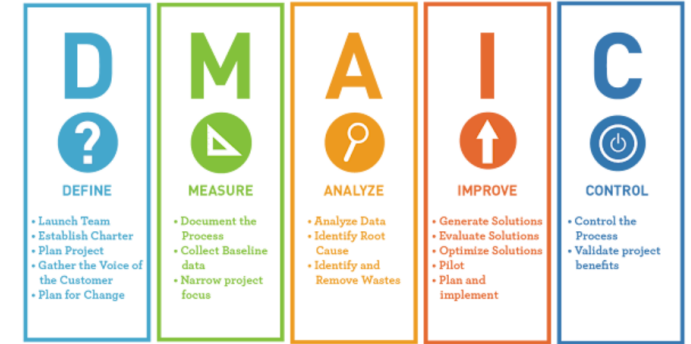


The Premise

- **Statisticians can be transformative partners—when engaged early.**
 - Often brought in after experiments are designed are locked.
 - Late engagement limits their impact.
 - Early collaboration reframes the problem itself.

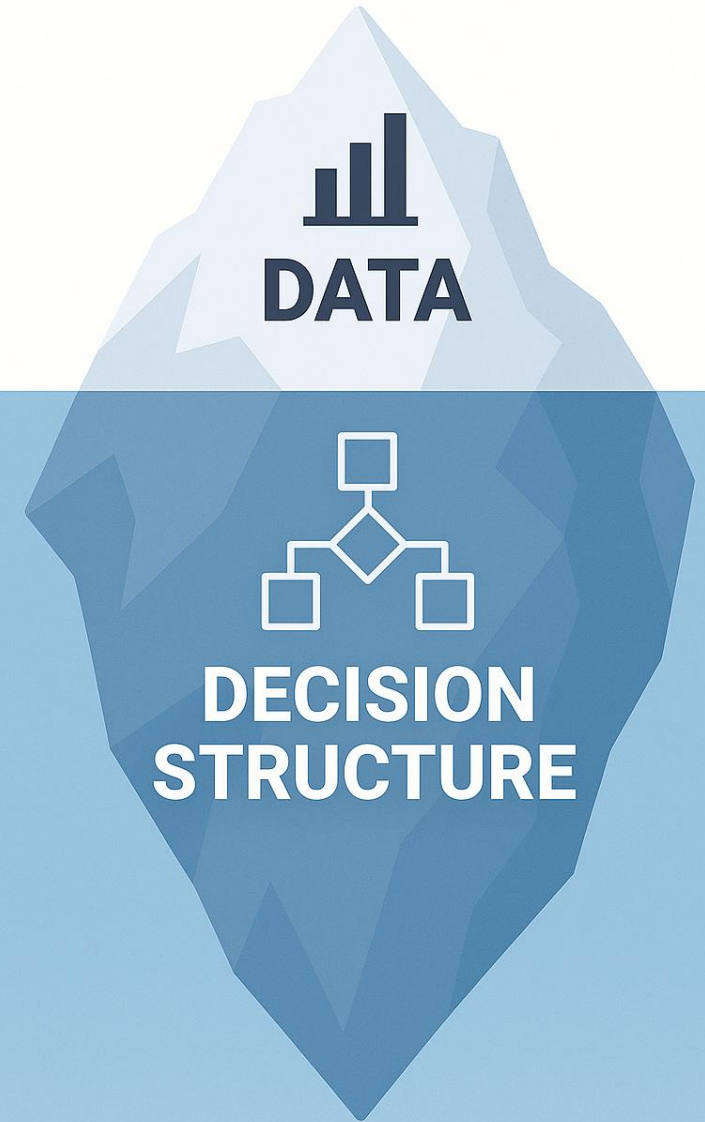


From the Sponsor's Seat



The Collaboration Gap

- **Why Engagement Happens Late**
 - Everyone thinks they are a statistician.
 - Everyone else finds talking to statisticians difficult.
 - Structural silos: stats viewed as support, not strategy.
 - Incentives favor delivery speed, not analytical rigor.
 - **Communication gaps—language barriers across disciplines.**
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Comparability

Framing the Right Question Early

Defined acceptance via tolerance intervals.

Simulated sample size and equivalence scenarios before study execution.

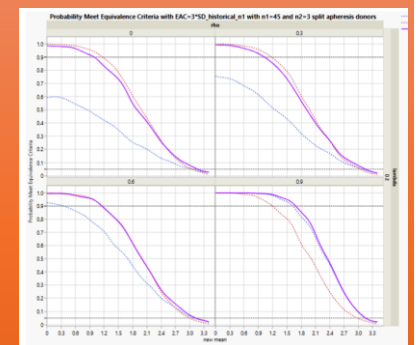
Outcome: faster regulatory alignment and confident go/no-go decision.

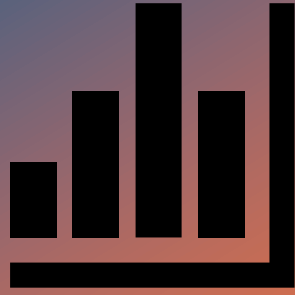


Define Critical Attributes

Apply appropriate statistical tools

Draw Conclusion in alignment with regulator expectations





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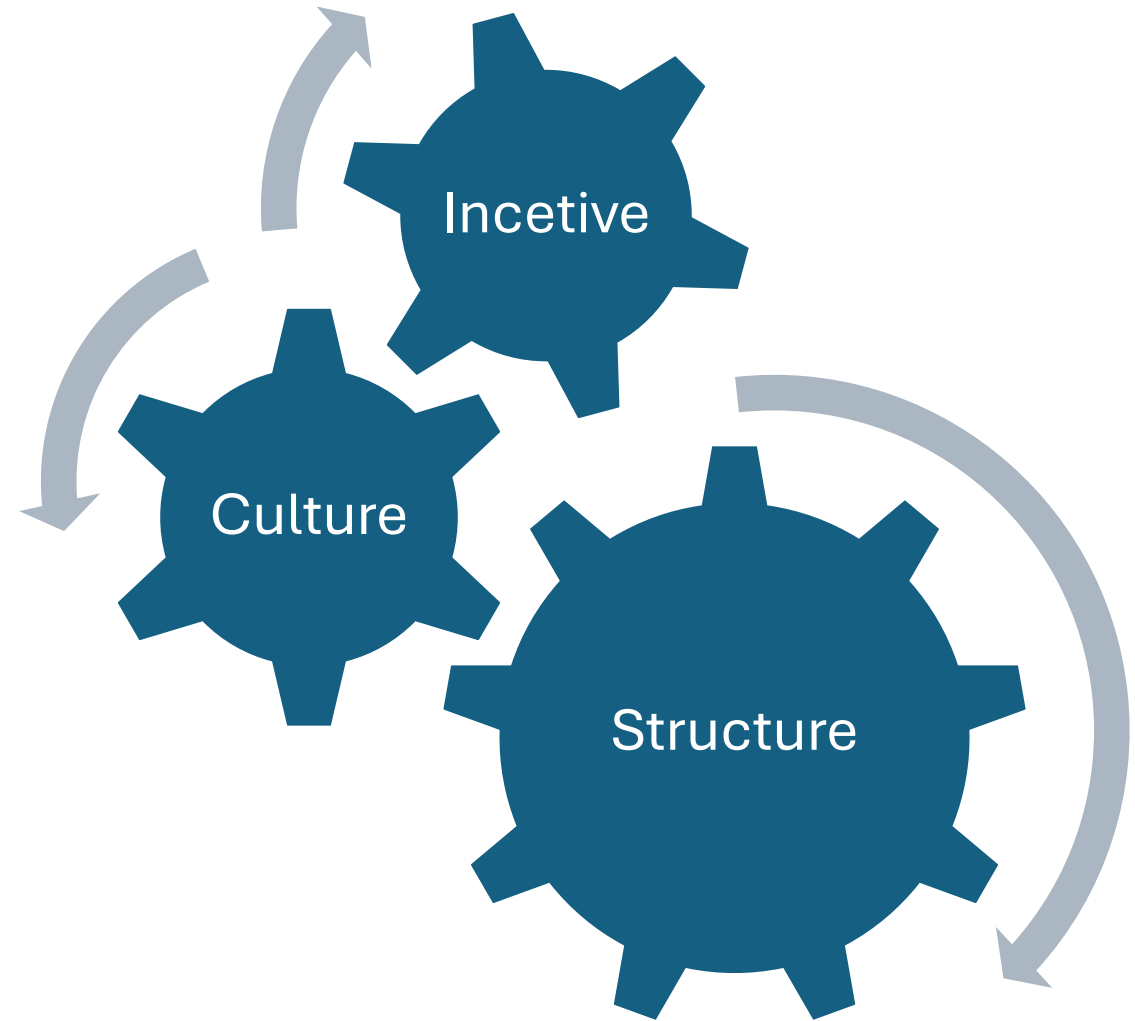


Inspection-Ready Analytics

- **Quality + Statistics = Credibility**
- Partnership built trending tools for stability & potency.
- Fat Pencil data analysis
- Outcome: smoother inspections, reduced surprises.

Leadership Lens

- **Leadership Levers for Early Engagement**
- **Structural:** RACI ownership for decision quality.
- **Incentive:** Fund prototypes and early analyses.
- **Culture:** “One slide of math” ritual.
- **Visual:** Gears labeled Structure | Incentive | Culture.



Building Trust in Partnerships



**PRACTICAL LEADERSHIP
TACTICS**



**EMBED STATISTICIANS IN
CORE TEAMS.**



**USE DECISION
CHARTERS FOR CLARITY.**



**EMPOWER RAPID "WHAT-
IF" SCENARIOS.**



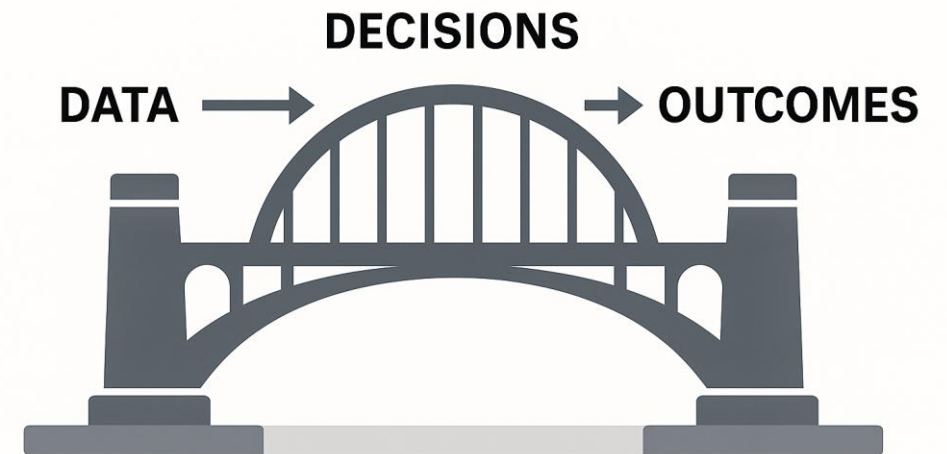
**INCLUDE STATS REVIEW
IN STAGE-GATES.**



**VISUAL: TRUST LADDER
OR HANDSHAKE
GRAPHIC.**

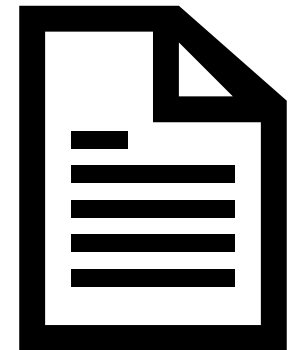
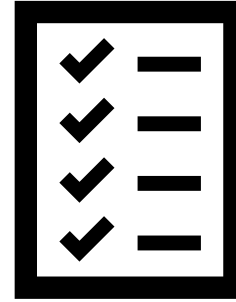
Lessons Learned

- **From Engineering to Executive Leadership**
- Data without context is noise.
- Cross-functional thinking beats siloed expertise.
- Trust and math are leadership tools.



Templates & Tactics

- **Practical Tools for Attendees**
- Decision Charter template (who, what, when, metrics).
- Statistical sign-off matrix.
- Small-n decision toolkit summary.



Call to Action

- **Reposition Statisticians as Strategic Co-Architects**
- Normalize early engagement.
- Make data a central part of the discussion. Educate the customer.
- Celebrate collaborative decision quality.

