



# The Stability Scientist and the Statistician – An Essential Partnership that Delivers

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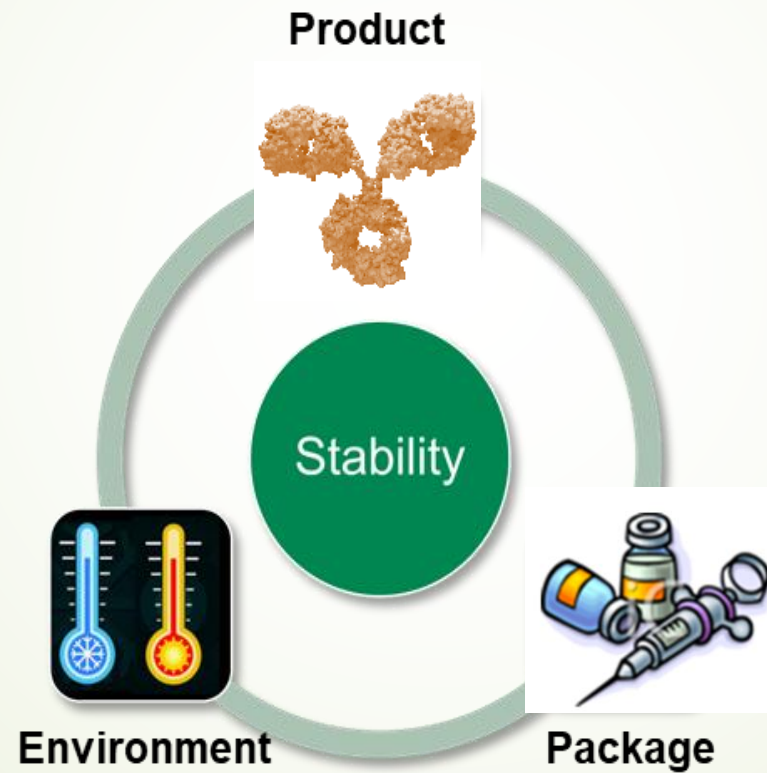
IABS 11<sup>th</sup> Annual Statistics Workshop – Big Tent Statistics

Session III: Collaboration and Recognition

Oct 22, 2025

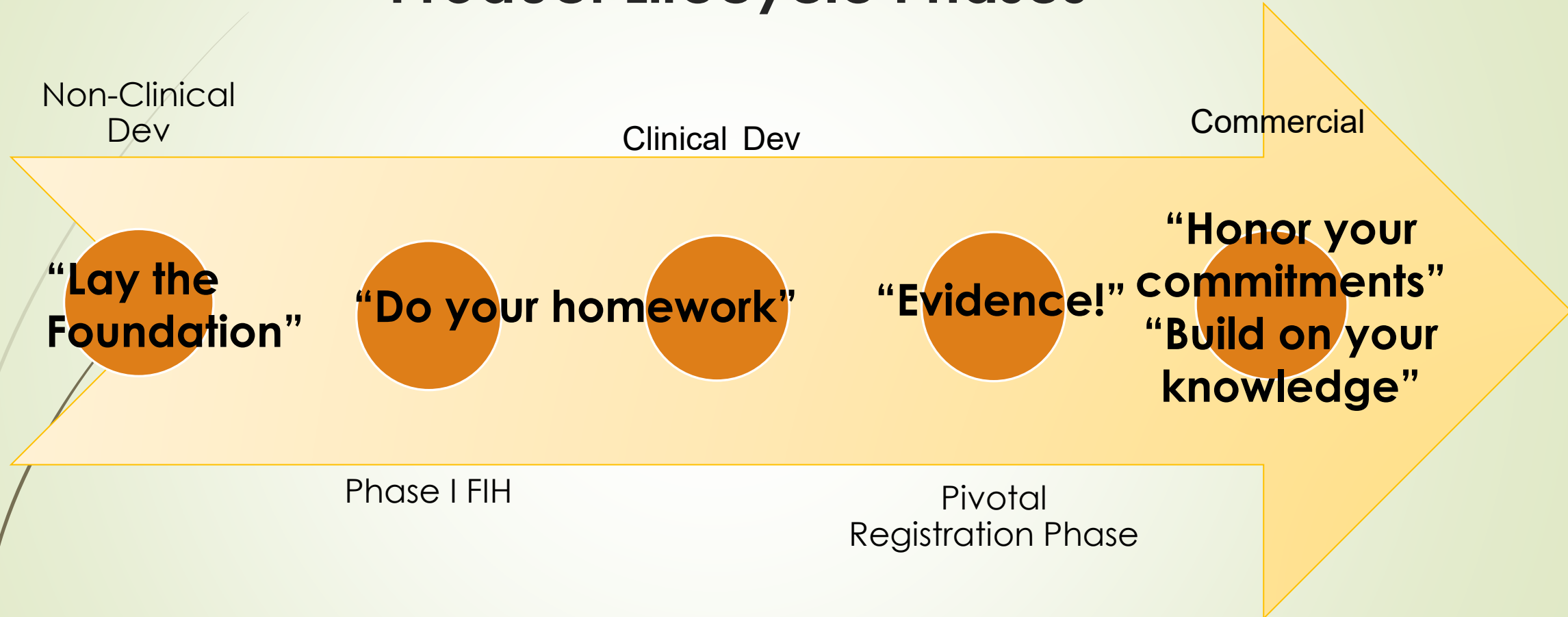
# Stability:

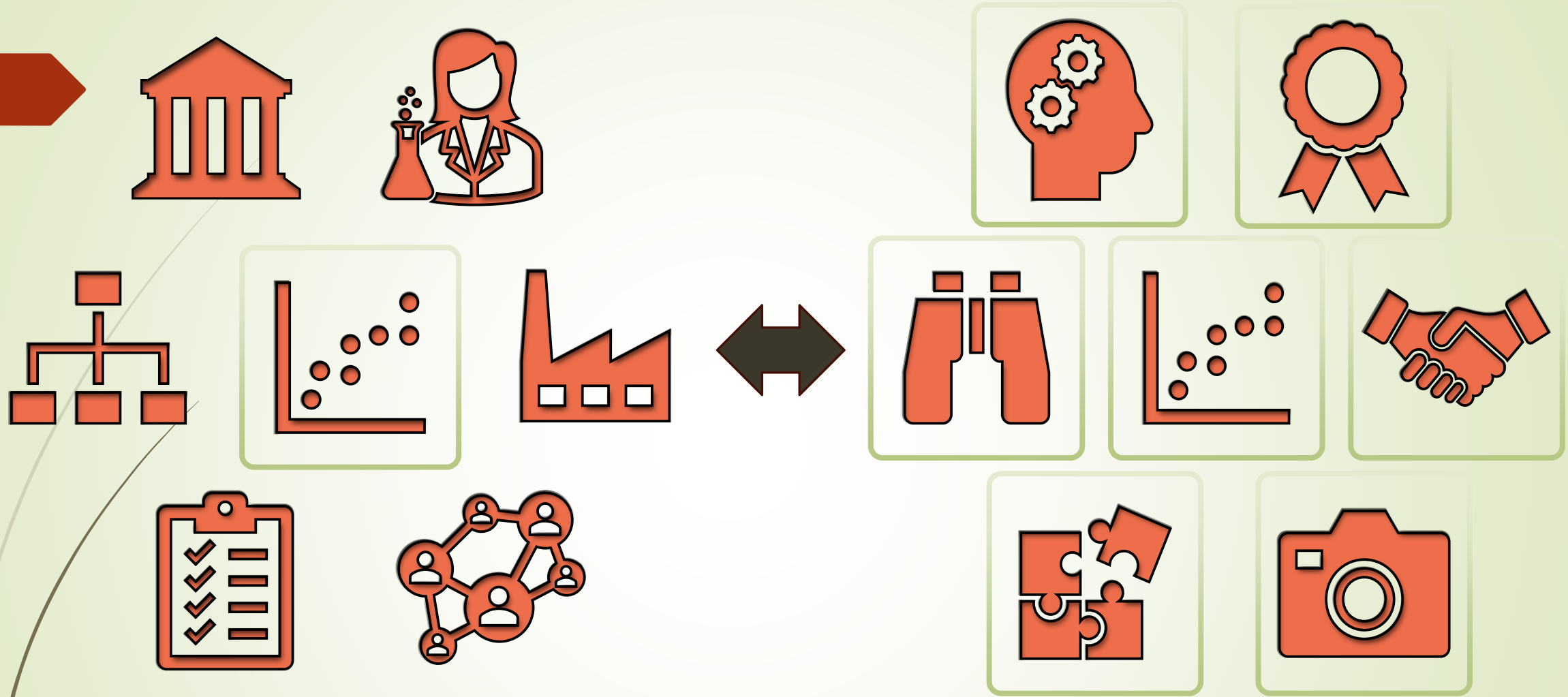
Describes the product that the patient sees



*The Statistician  
helps the  
Stabilitarian  
understand and  
tell the story*

# “WHAT” DEPENDS ON “WHEN”: Product Lifecycle Phases

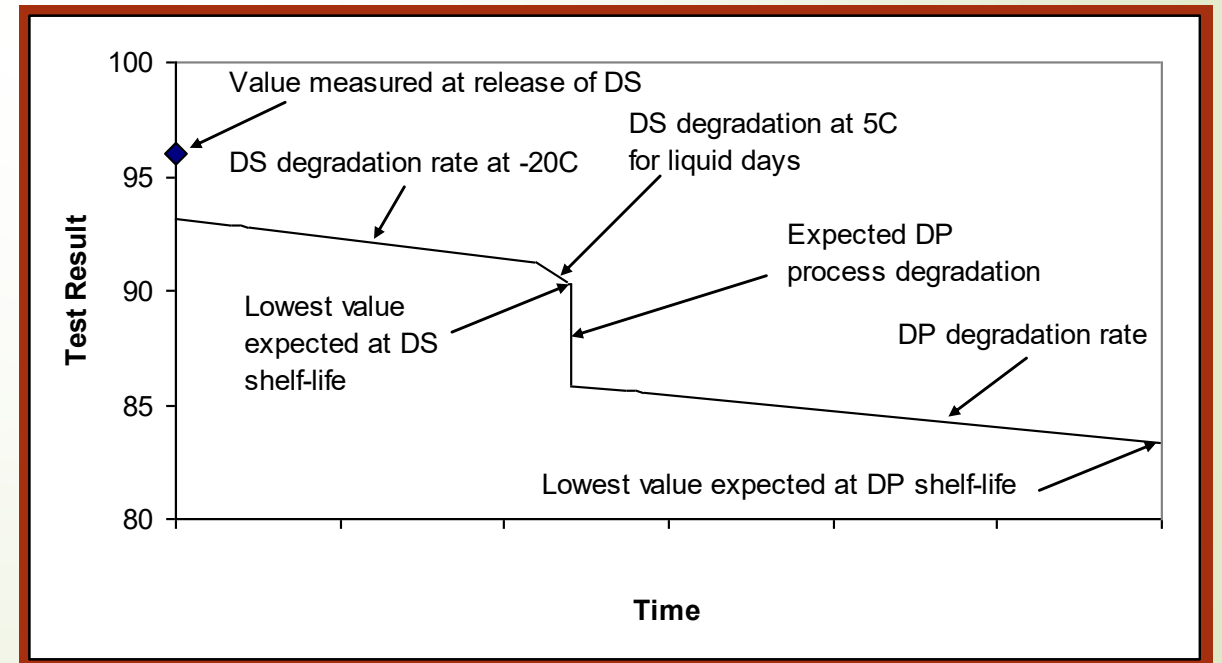
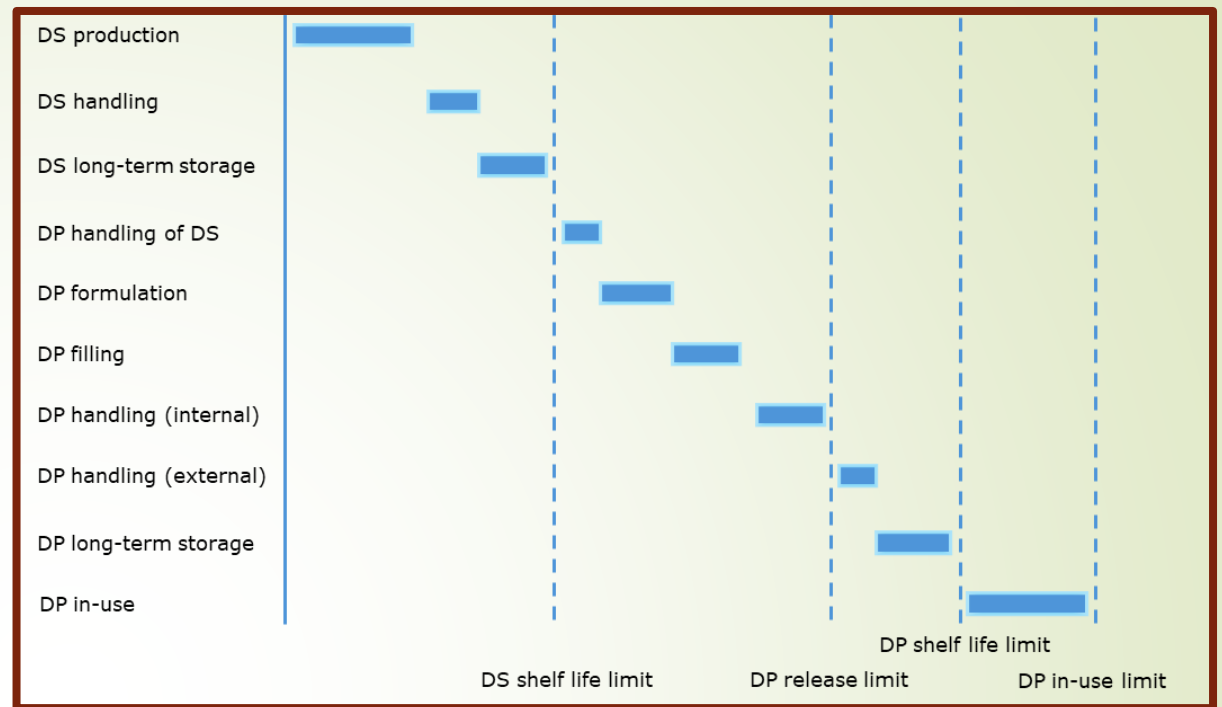




**“Who” and “What” are also inter-related**

# Application Examples: End to End

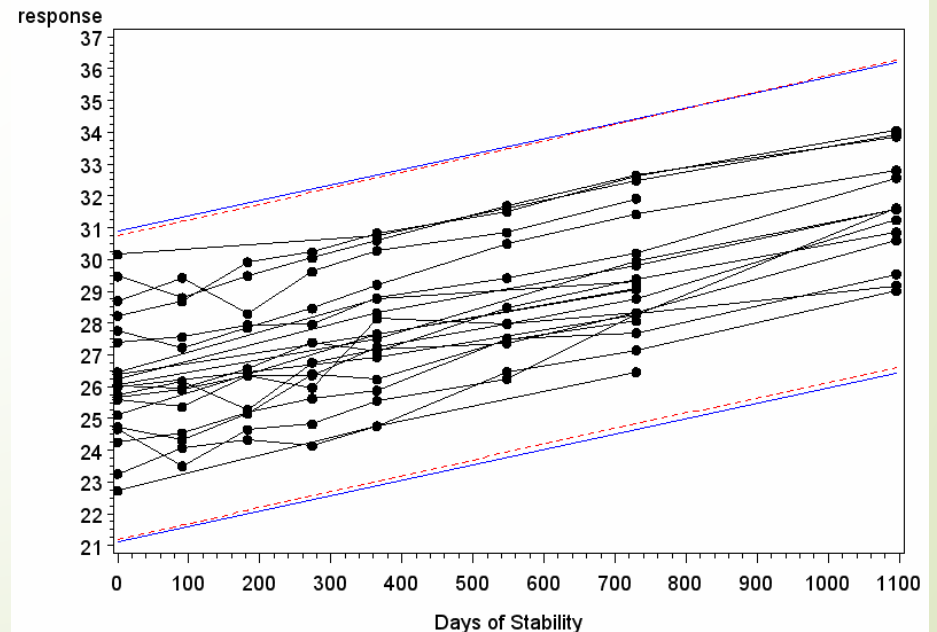
- Specifications
- Prediction Models
  - Extrapolation for long-term degradation/ SL
- Prior Knowledge
- DS to DP control points + EOSL support
- Stability “Budget”



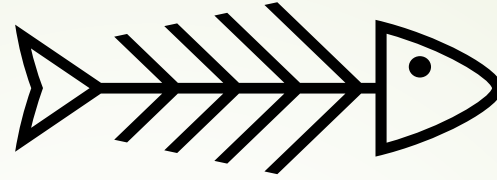
# Application Examples: Trending

- Trending program for individual OOT identification & response
- PQR
  - Comparisons
  - Drifts or shifts, trends of trends
- Opportunities
  - Shelf-life extensions
  - Smart stability – leaning out the stability program

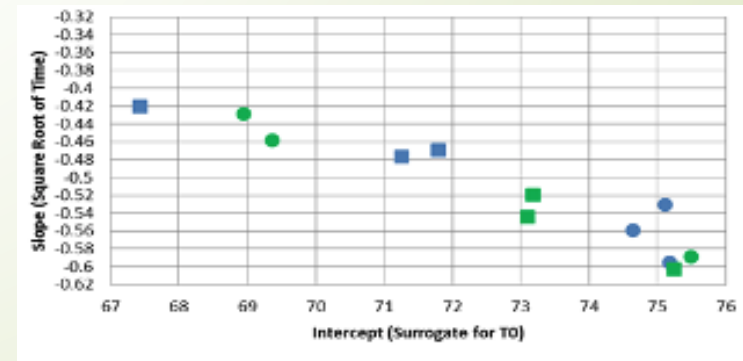
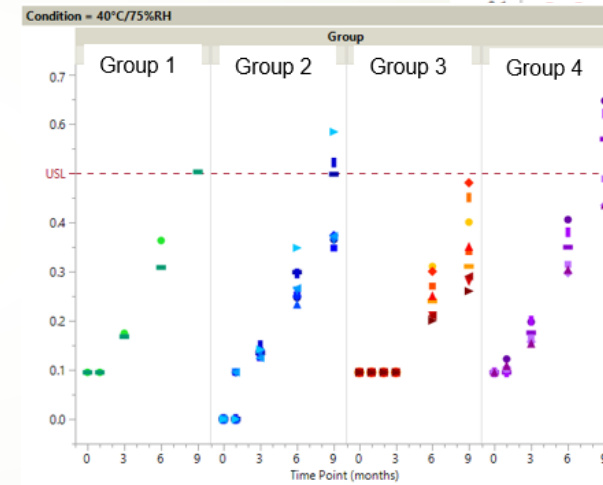
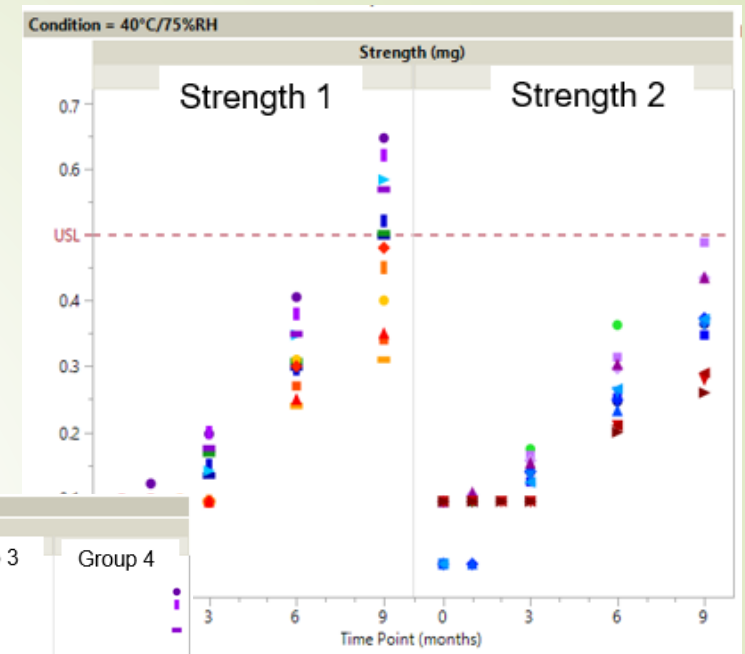
- Trending approaches can range from simple to complex
- Data sources may be combined – for example, historical stability data and analytical method data combined with batch data to determine limits w/in program
- Trending approaches may rely on the current batch regression, historical data or both
- Comparison of rates may also be used to support post-approval comparability



# Application Examples: Investigations



- Correlations to assist in fishbone (Ishikawa) diagram for root cause analysis
- Identify visual or simple statistical trends, determine where to look more closely and apply more refined statistical analyses.
- Probability of OOS and/or supportable shelf-life assessment





# Communication between Statistician and Stability Scientist is Critical

- Understanding each others language

*“Reserved Words”*  
*Condition*  
*Significant Change*  
*Interval*

- Mutual understanding of the challenges and constraints in the generation and evaluation of stability data

*Confidence*  
*Number of Lots*

## What is our research question?

# The Statistician as Partner, Collaborator, and Leader

- Standardized approaches are established and may be proceduralized
- Some applications can be routinely applied within the quality system, with alternatives justified as needed
- Statisticians increase the capability of stability partners (statistical acumen)
- Statisticians serve on product development teams (CMC teams or sub-teams) especially for accelerated programs
- Technical expertise, time and quality of solutions are optimized by early involvement of statistician for investigations or non-routine work
- Statisticians identify and work with stabilarians to identify and incorporate innovative approaches as new standards,



**The evolution of science & risk-based stability approaches requires a close collaboration**

# ICH Revision Process

## Q1/Q5C



Updates to and introduction of international guidelines provide new opportunities (and expectations)



Concept Paper, Business Plan    Consensus Building  
Expert Working Group Forms    Develop Draft Guideline



Draft Guideline Adopted



Public Consultation



Adoption of Final Guideline

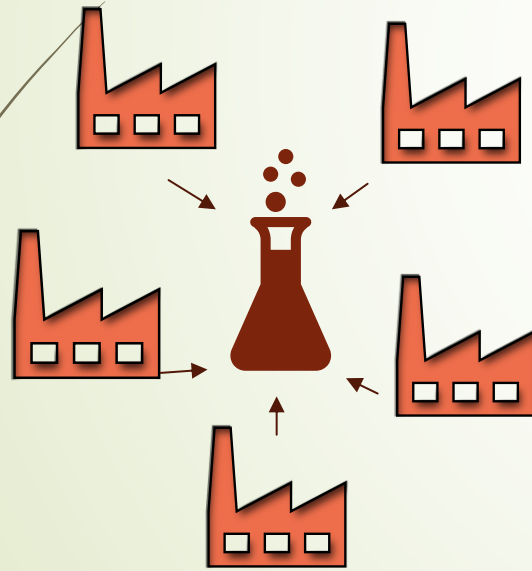
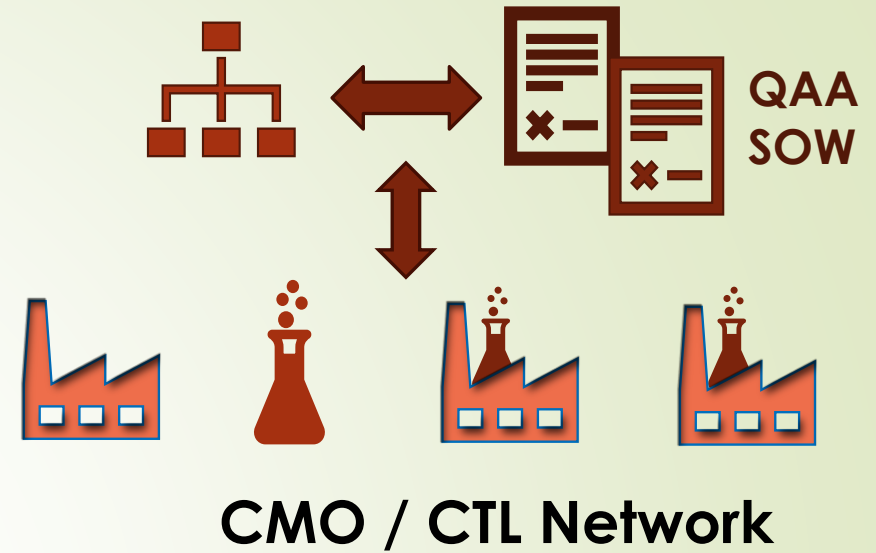


Implementation of Guideline by Regulators

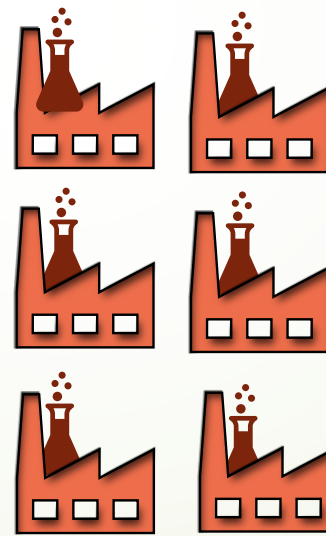
[Reference: ICH Process of Harmonization](#)

[Reference: ICH Quality Guidelines \(click on Q1/Q5C EWG\)](#)

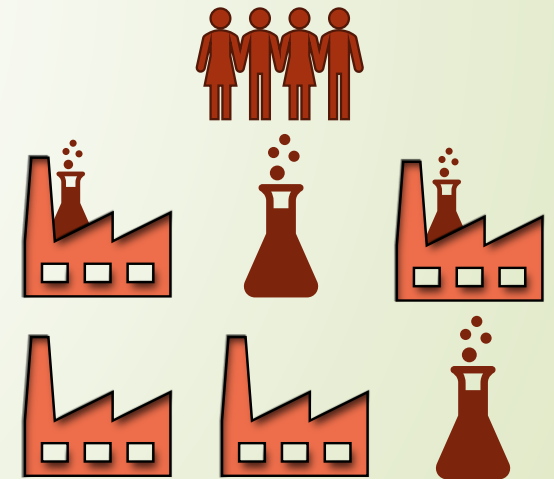
# Size and Organizational Design of Manufacturing / QC Network Influences the Distribution of Activities and Oversight – And Access to Statisticians



Internal  
Stability Hub



Internal Site  
Focused



Global  
Network



# ***The Challenge for Us...***