



2024 CDISC + TMF  
US INTERCHANGE

**PHOENIX/SCOTTSDALE**



23-24 OCTOBER: CONFERENCE & EXPO | 21, 22, 25 OCTOBER: TRAININGS

## **Navigating Change Resistance: Understanding Resistor Profiles and Strategies for Effective Change Management**

Meghan Zuchlewski and Jim Markley, Just in Time GCP

# Meet the Speakers

## Meghan Zuchlewski

**Title:** Operations & Change Lead

**Organization:** Just in Time GCP

Meghan has leveraged her Masters in Organizational and Business Psychology with her certification in Change Management from Prosci to develop a change management methodology that helps clients navigate transformative changes and ensure smooth transitions and lasting positive impact.

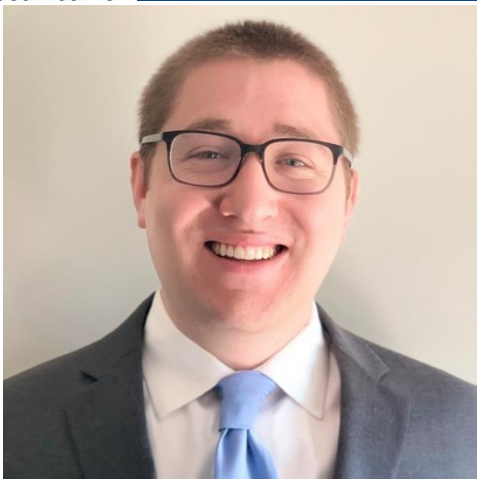


## Jim Markley

**Title:** Associate Director, Consulting

**Organization:** Just in Time GCP

Jim has been in the industry for over 10 years starting at a clinical research site, moving to a large CRO, and then moving into consulting at JiT. He is responsible for helping clients optimize and improve business processes to ensure TMF Completeness and Inspection Readiness. He is a member of the Controlled Terminology and Risk Initiatives within CDISC.





# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *The author(s) have no real or apparent conflicts of interest to report.*



# Introduction

Change & the Trial Master File

Change is  
constant in  
the TMF  
World...





# What Does Resistance Stem From?

70% of change initiatives fail due to resistance from employees

Employees who will experience a disruption of routine or current ways of working

Employees who expect more work because of the change

Those who advocated for a particular alternative, but a different selection was made

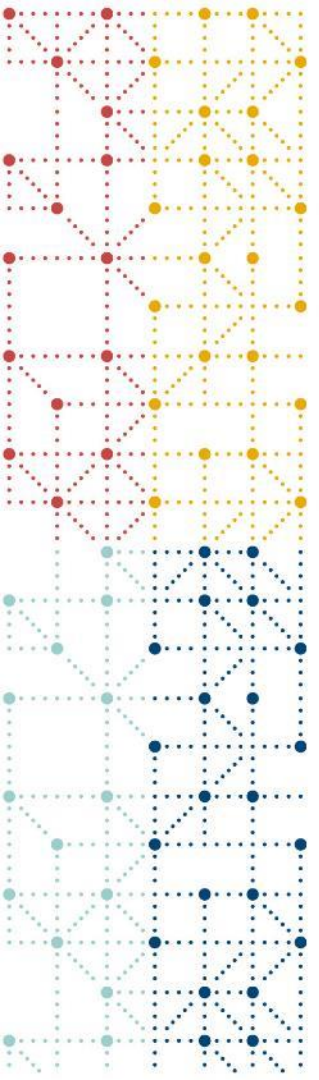
Employees with a lack of awareness of why the change is needed

Change fatigue, becoming overwhelmed by constant change

Fear of job loss and uncertainty or an employee's personal, family, or professional situation

Lack of leadership support

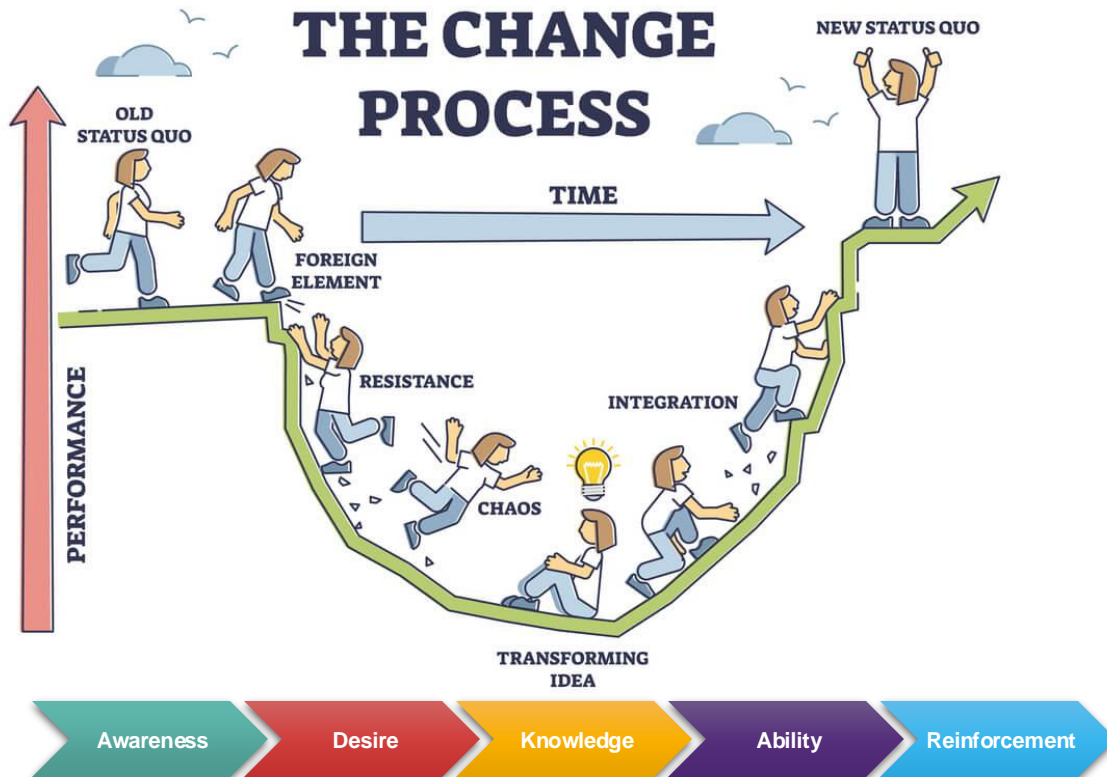
History with change (past failures/flavor of the month)



# Understanding Resistance

Reactions to Change and Identifying Resistance

# Moving Individuals Through Change...





# Reactions to Change Takes Many Forms

- Fear of change is natural and can create stress, even if the future state will clearly generate improvement



# Understand Resistance

- There are 3 levels of resistance:

1

## Level 1: I don't get it...

- I don't understand the purpose of the change or how to change
- Mitigation: Provide information and facts/figures, and evaluate effectiveness of communications and language used

2

## Level 2: I don't like it...

- Emotional reaction to change
- Mitigation: Emphasize the advantages of change for individuals

3

## Level 3: I don't like or trust you...

- Lack of trust or confidence in the person(s) explaining the change
- Mitigation: Engage in discussion to understand questions and concerns, include in implementation, and rebuild trust through inclusive environment

# Identify Resistance



## Observation & Behavior

- Monitor attendance and engagement during informational sessions (training, office hours)
- Observe employees not adopting to the new way of working



## Change Agent Network

- Use to identify key resistors of change and gather feedback on the change approach within their respective groups



## Leaders & Managers

- Communicate with line managers to learn how their direct reports view the change and understand challenges that they are facing with the change



## Data collection

- Use surveys to collect data and gauge awareness of the change and desire (or lack thereof) to support the change



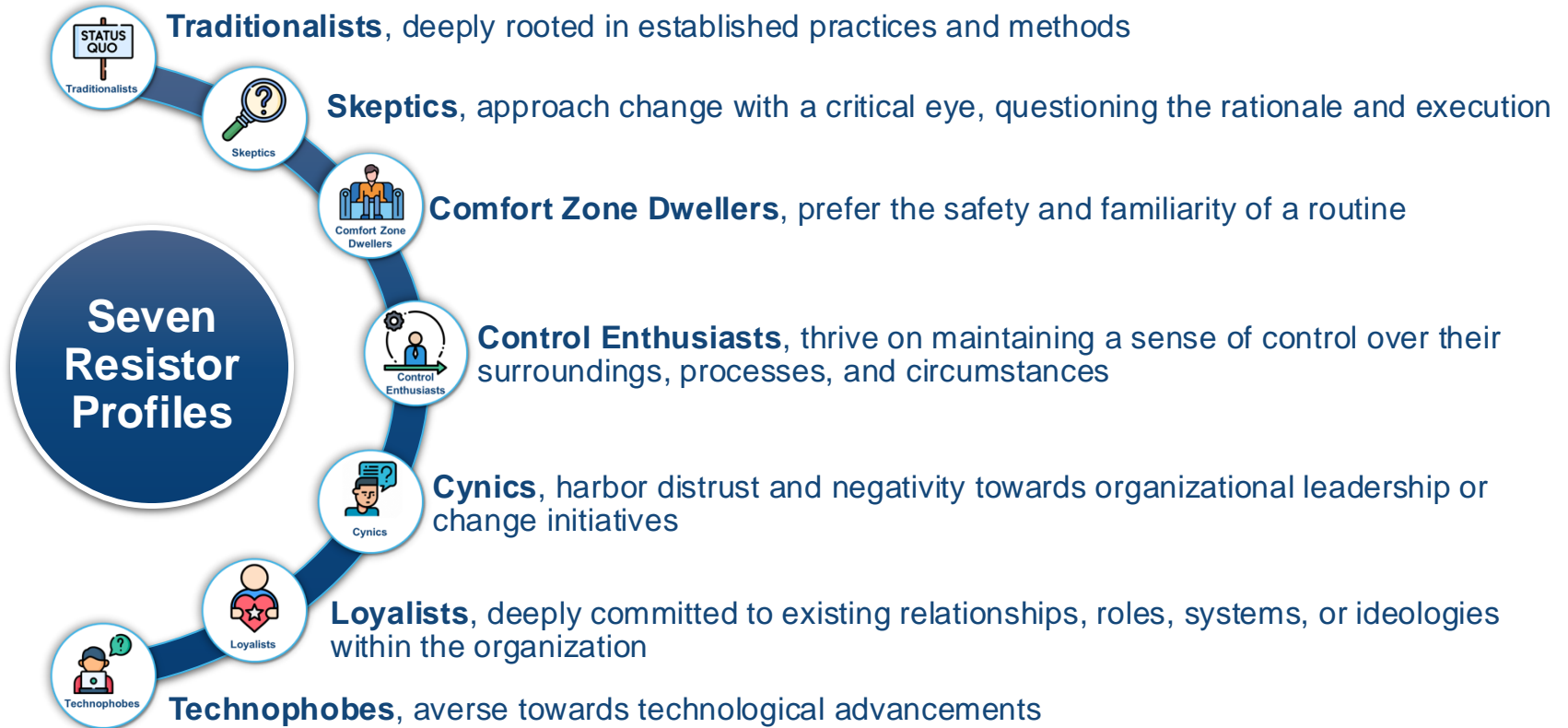
How to Identify Resistance



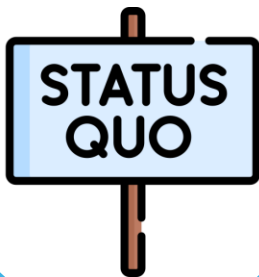
# Managing Resistance

The Seven Typical Profiles of Change Resisters

# The Seven Typical Profiles of Change Resistor



# Traditionalists



## About:

Traditionalists are deeply rooted in established practices and methods. They value continuity and stability, often viewing change as disruptive and unnecessary. They prefer the familiarity of the status quo and may resist any deviation from established norms.



## How to Identify Resistor

- “That’s not the way **we** do things around here”
- Resist any deviation from status quo with vocal and open disagreement



## Effective Use in a Change Initiative

- Leverage their understanding of current processes and ways of working when change involves process optimization
- Utilize their knowledge to uncover pain points



## Strategies to Overcome Resistance

- Provide opportunities for involvement and input to ensure their perspectives are heard and valued
- Highlight the benefits of the change and WIIFM



# Skeptics



## About:

Skeptics approach change with a critical eye, questioning the rationale behind the change. They may harbor doubts about the effectiveness or benefits. They may seek evidence and often require thorough explanations or demonstrations to overcome their reservations.



## How to Identify Resistor

- Vocal opponent with doubtful questions
- Potential for sabotage through type of questions and rumors/gossip



## Effective Use in a Change Initiative

- Involve in pilot programs or test groups to demonstrate the effectiveness of proposed change



## Strategies to Overcome Resistance

- Provide clear, evidence-based explanations on the need for change
- Openly address their questions and concerns to address reservations

# Comfort Zone Dwellers



## About:

Comfort Zone Dwellers prefer the safety and familiarity of a routine and predictable environment. They resist change due to fear of the unknown or uncertainty about their ability to adapt. They may feel overwhelmed by change and perceive it as a threat to their sense of security.



## How to Identify Resistor

- Vocal concern about impact to routine or current ways of working
- May display decreased productivity



## Effective Use in a Change Initiative

- Involve in training review sessions, to understand where more detail may be needed



## Strategies to Overcome Resistance

- Communicate early and often; consider WIIFM
- Provide ample resources and support to build confidence and ability through trainings, as well as Office Hours to address additional questions/concerns
- Celebrate successes to reinforce change

# Control Enthusiasts



## About:

Control Enthusiasts thrive on maintaining a sense of control over their surroundings. They resist change that diminishes their autonomy or disrupts routines. Control Enthusiasts may perceive change as a loss of power, leading them to resist yielding control to external change.



## How to Identify Resistor

- “That’s not the way *I* do things around here”
- Standoffish demeanor due to perceived loss of control



## Effective Use in a Change Initiative

- Provide sense of control through some involvement in decisions making or material review (process maps, training, etc.)



## Strategies to Overcome Resistance

- Clarify roles and responsibilities to alleviate concerns about loss of control
- Build trust through open-door policy and sharing information as transparently as possible

# Cynics



## About:

Cynics harbor distrust or negativity towards leadership or change initiatives. They may perceive change as driven by ulterior motives or believe that it will not result in tangible benefits. Cynics may resist change as a form of protest or defiance against perceived injustices or biases.



## How to Identify Resistor

- Tendency to bring up past change failures
- Potential for sabotage by spreading rumors, gossip, and negativity



## Effective Use in a Change Initiative

- Include in discussions of change management strategy to demonstrate dedication to the success of the change and individual employees



## Strategies to Overcome Resistance

- Address grievances with honesty and transparency
- Provide evidence-based explanations on the need for change and benefits of the change
- Lead with integrity and commitment to organizations values and strategic objectives

# Loyalists



## About:

Loyalists are deeply committed to existing relationships, systems, or ideologies. They resist change that threatens to disrupt these bonds or values, viewing loyalty as paramount. Loyalists may fear alienation or betrayal if they align themselves with change efforts that conflict with their allegiances.



## How to Identify Resistor

- Decreased productivity
- Decreased presence and involvement



## Effective Use in a Change Initiative

- Foster sense of belonging and involve in the change initiative according to their skillset



## Strategies to Overcome Resistance

- Communicate early and often the benefits and reasoning of the change, as well as gratitude for previous ways of working
- Lead with integrity and commitment to organizations values and strategic objectives
- Build trust through open-door policy

# Technophobes



## About:

Technophobes are adverse towards technological advancements. They may feel overwhelmed or intimidated by new technology, perceiving it as too complex or intrusive. They may resist adoption due to a lack of confidence in their ability to use technology effectively or concerns about privacy and security.



## How to Identify Resistor

- Decreased productivity, potentially caused by inability to work with technology



## Effective Use in a Change Initiative

- Involve in training review sessions, to understand where more detail may be needed

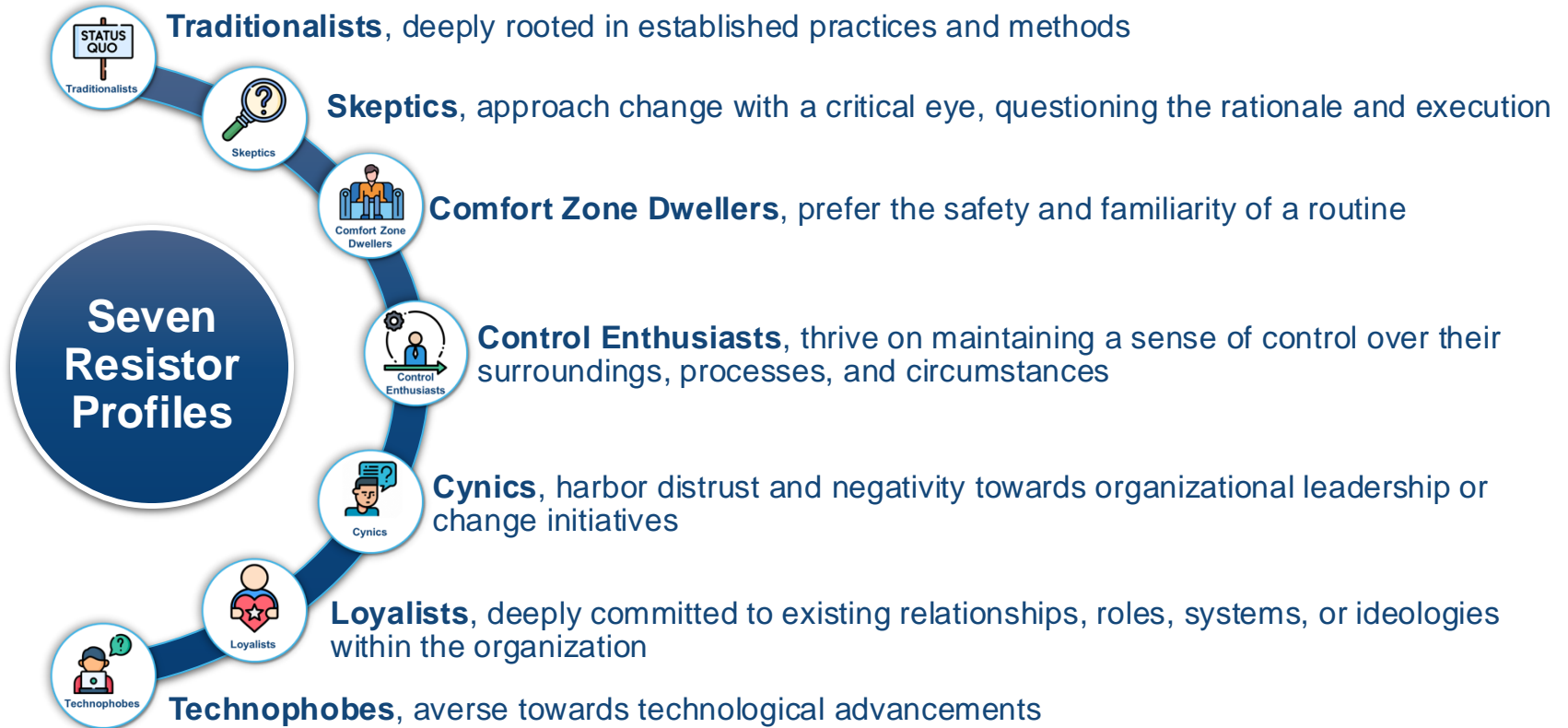


## Strategies to Overcome Resistance

- Provide support channels and encouragement to build confidence
- Provide ample training resources and simulation eLearning's, if possible
- Address concerns about privacy and security through clear policies



# The Seven Typical Profiles of Change Resistor



# Thank You & Questions

We'd love to hear from you...Come speak with us at the Just in Time GCP booth!

Check out our blog series on the Just in Time GCP website,  
**Navigating Change: A Four-Part Blog to Change Management**



Blog 1: Understanding the Need for Change Management