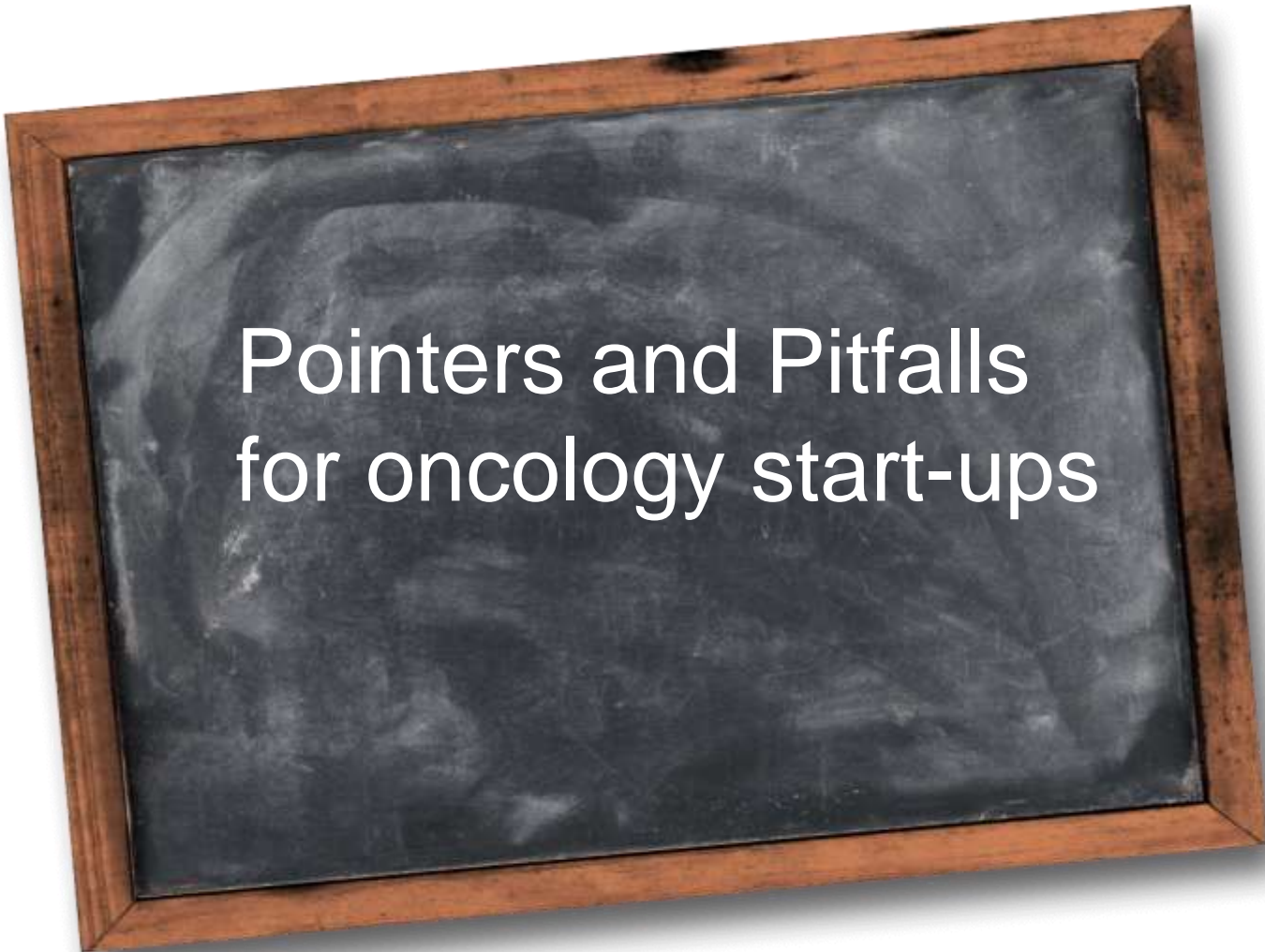


# Overview and Roadmap

**Jeff Summers**

Associate Director Translational Sciences  
Office of Oncologic Diseases  
CDER | US FDA

March 30-31, 2021

A wooden-framed chalkboard with the title "Pointers and Pitfalls for oncology start-ups" written in white chalk. The board shows signs of use with some smudges and a dark, textured surface.

# Pointers and Pitfalls for oncology start-ups

Tumor Cell

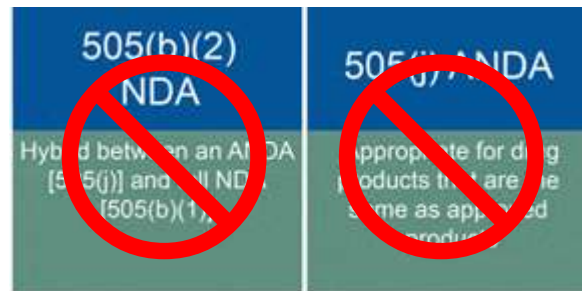
Toxicity



Safety

Healthy Cell

# Course Syllabus does not include



# Fair and Level Playing Field



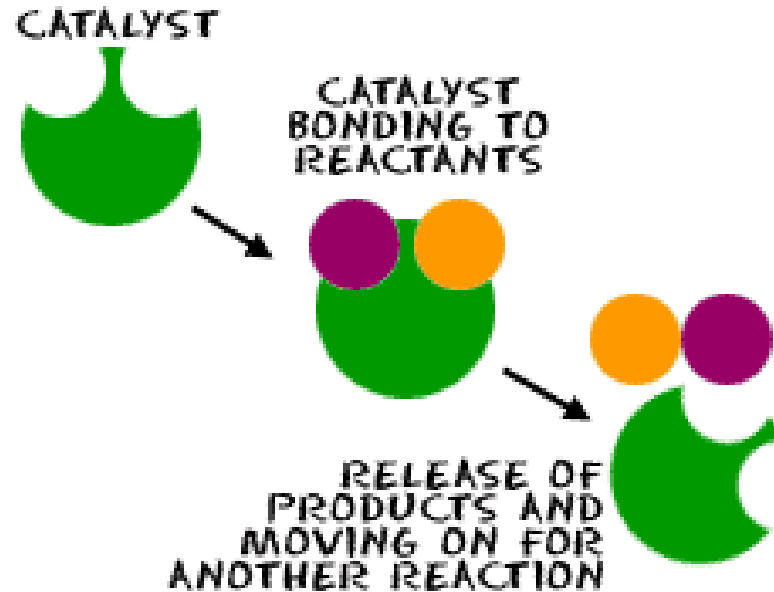
Insert your company name here







# Project Catalyst



# Project Catalyst





# Let's look at the roadmap

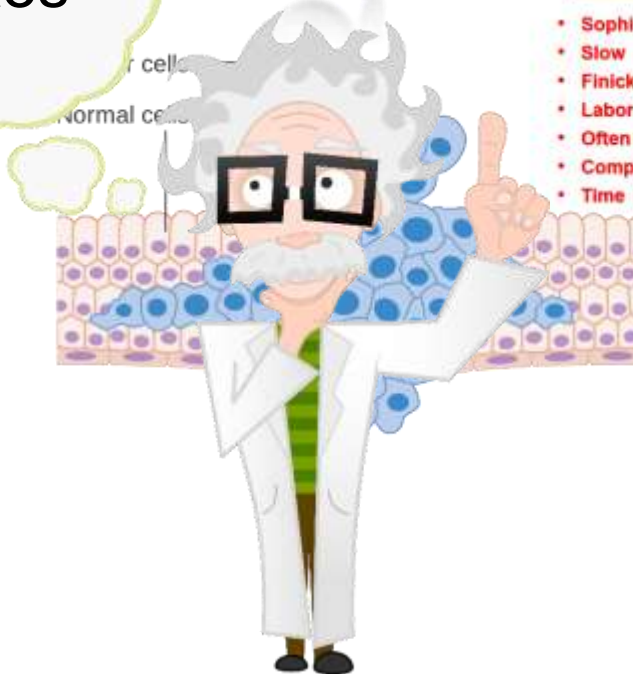


# Regulatory Flexibility



# Regulatory Flexibility

Critical Quality Attributes



## Strategies to Identify Predictive CQAs



# Regulatory Flexibility

