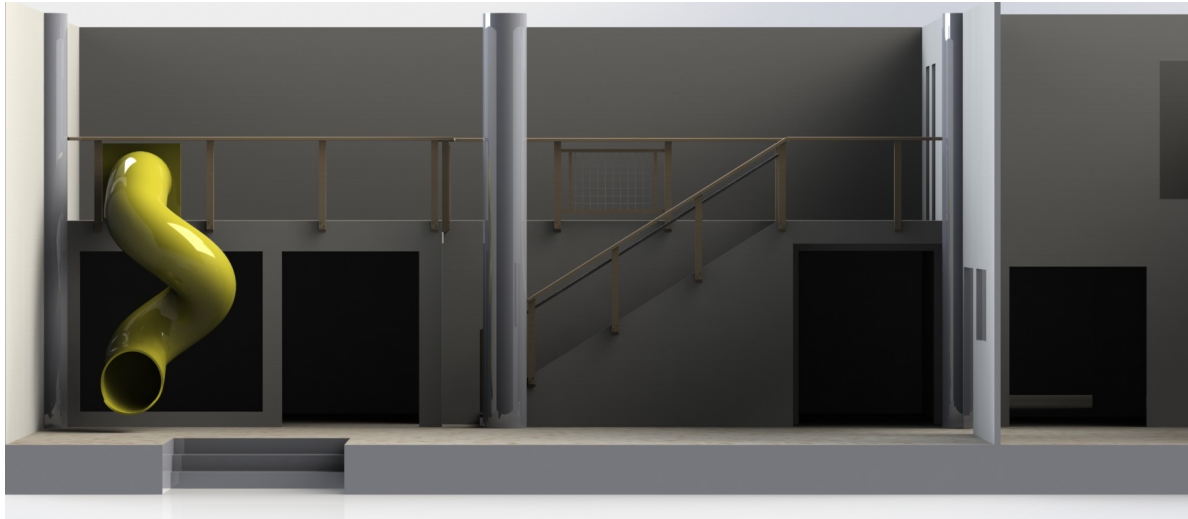


# Navigating clinical and regulatory efforts in startup environments

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AMDM Focus Meeting 2022

What is a startup?



What is a startup?



IPO

“Disrupt”

“Move fast and break Things”

Unicorn

What is a startup?



## Mistakes were made...

1. Attempting to handle too many functions on your own and underestimating expertise required
2. Spending too little time on program management
3. Overlooking data and data visualization

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# Profile of regulatory and clinical lead

## **Experience**

2 years: Process engineer at semiconductor company

1 year: Research assistant in biomaterials/bioE lab at UCSF

1 year: Postdoctoral research at Stanford in tissue engineering

1 year: Marketing intern at UCSF Innovation Ventures

1 year: Field application scientist at Essen Bioscience (live cell imaging system for researchers)

## **Education**

BS ChemE UC Berkeley

PhD Biomaterials/Bioengineering UCSF

# The value of regulatory experts

- Develop intended use
- Refine regulatory strategy to maximize chances of success
- Highlight potential pitfalls



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## Where it can go wrong... specifically

- Choosing a CRO that does not have experience in your intended use and indications for use
- Creating clinical development plans without regulatory input

A man with dark hair, wearing a dark shirt, is shown from the chest up. He is holding a mobile phone to his ear with his right hand. His facial expression is one of concern or worry, with furrowed brows and a slightly open mouth. The background is dark and out of focus, suggesting an indoor setting at night.

**WHAT I DO HAVE ARE A VERY  
PARTICULAR SET OF SKILLS**

**SKILLS I HAVE ACQUIRED OVER A  
LONG CAREER**

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# Benefits of implementing data visualization



- Team engagement
- Organizational efficiency
- Faster analysis
- Informed decision-making







# Mistakes were ~~made~~ corrected...

- ☑ 1. Attempting to handle too many functions on your own and underestimating expertise required – **SMEs**
- ☑ 1. Spending too little time on program management - **TEAM**
- ☑ 2. Overlooking data and data visualization - **PLAN**

