

A Reflection on Today's Seminar's Title

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Regulatory Do's and Don'ts: Tips from FDA
September 4, 2024

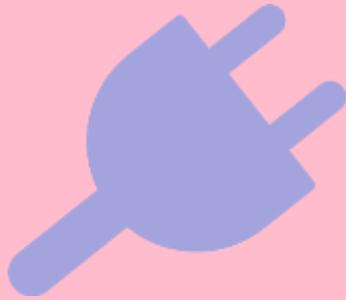
Overview

- A positive spin on a questionable Do's and Don'ts webinar title (probably my fault)
- The one imperative action to take for success (with a caveat)
- How to accomplish that task (its not AI)
 - Read
 - Listen
 - Learn
- And as Picard would say—Engage

The Do's and Don'ts ?

- These are not your Do's and Don'ts, but the FDAs.
- The OCE's primary "Do"

The Oncology Center of Excellence



The Do's



- These are not your Do's and Don'ts, but the FDAs.
- **The OCE's primary Do: Approve Safe and Effective Oncology Drugs**
- To provide a fair and level playing field

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- These are not your Do's and Don'ts, but the FDAs.
- The OCE's primary Do: Approve Safe and Effective Oncology Drugs
- To provide a fair and level playing field
- To help guide you in meeting regulatory standards

The Don'ts ?

- Discovery
- Consultants
- Disclosure
- Financial and Intellectual Property

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The Don'ts



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The Don'ts



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The One Action for Success

(with a caveat)



- And the number one action to take is...

Adage of successful drug development

FDA

Start with one
that works



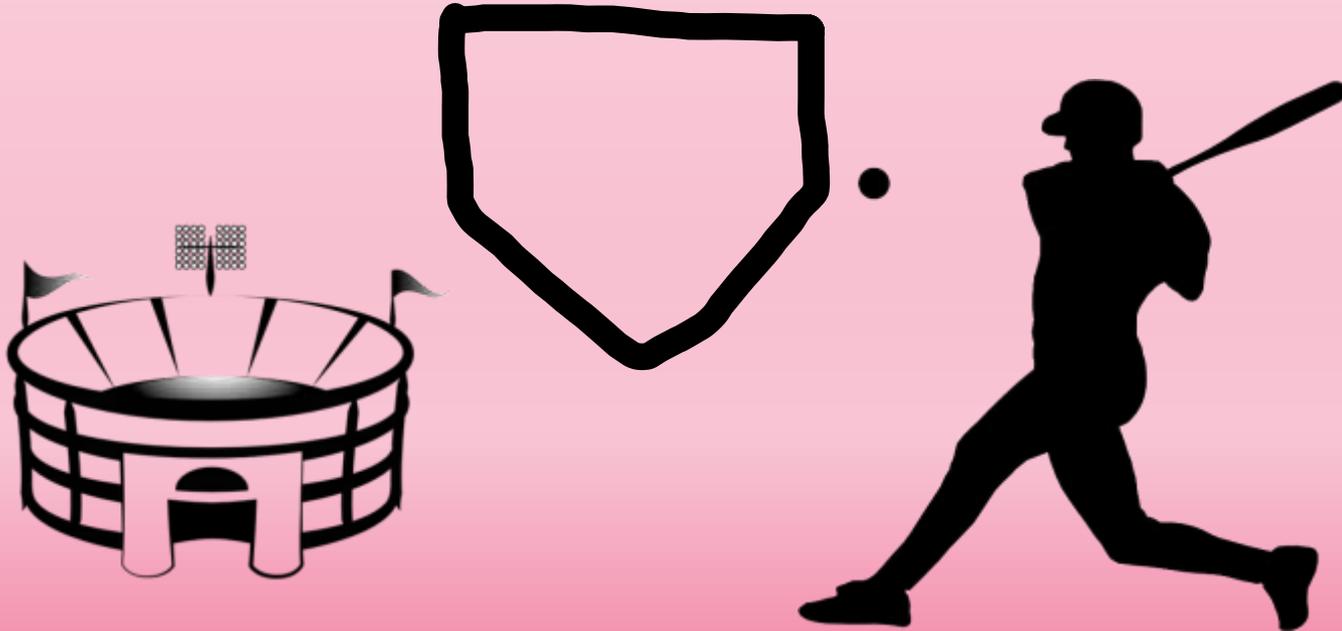
The One Action for Success

(with a caveat)



- And the number one action to take is...

Step up to the plate



Accomplishing that task



- Take-home point number 1

Read the relevant FDA and ICH Guidance Documents

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FDA Small Business Assistance

FDA

FDA

- Read the FDA and ICH Guidance Documents
- Listen/Watch/Learn

Center for Biologics Evaluation and Research (CBER)

Office of Communication, Outreach and Development (OCOD)

Division of Manufacturers Assistance and Training (DMAT)

Manufacturers Assistance and Technical Training Branch (MAT)

800-835-4709 or 240-402-7800

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Center for Drug Evaluation and Research (CDER)

Office of Communications

Division of Drug Information (DDI)

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Center for Devices and Radiological Health (CDRH)

Office of Communication and Education (OCE)

Division of Industry and Consumer Education (DICE)

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Accomplishing that task

- Read the FDA and ICH Guidance Documents
- Listen/Watch/Learn
OCE Project Catalyst Bench to Bedside Chats



Accomplishing that task



SEED

Helping Innovators Turn Discovery Into Health

Regulatory support information offered by Innovator Support Services, Small Business Education and Entrepreneurial Development, NIH Office of Extramural Research:

- Small Molecule and Biologic Drugs
- Medical Devices
- Diagnostics

Accomplishing that task



- Take home point number 2

You the audience



Creative scientist

Physician scientist

Day Job and then some

Patient responsibilities

Teaching responsibilities

Committee responsibilities

Publishing expectations

Grad students and Post Docs

- You have made interesting observations in your science
- Exploit those observations against cancer and translate the science into medicine
- Hopefully--you have done the Crux activity experiment

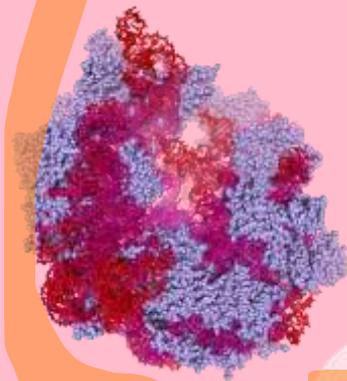
You the audience



Formed a company to make a product to treat cancer



START-UP



Accomplishing that task



- And take-home point number 2 is..

Take home point number 2



- Most founders of biotech start-ups realize this quickly: They have a Day Job and they like their Day job
- Maybe you could do it all
 - in your academic lab
 - in the rented wet-space you just leased last week
 - maybe you and the smattering of actual employees of said start-up could learn on the fly--
- But you are likely to make multiple mistakes in navigating the “enterprise” of drug development
- If you do not have the expertise in house

Carefully consider bringing a
competent regulatory consultant
to the table

Engage



- With colleagues (oncology subspecialists and FIH clinical trialists)

Engage

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- FDA

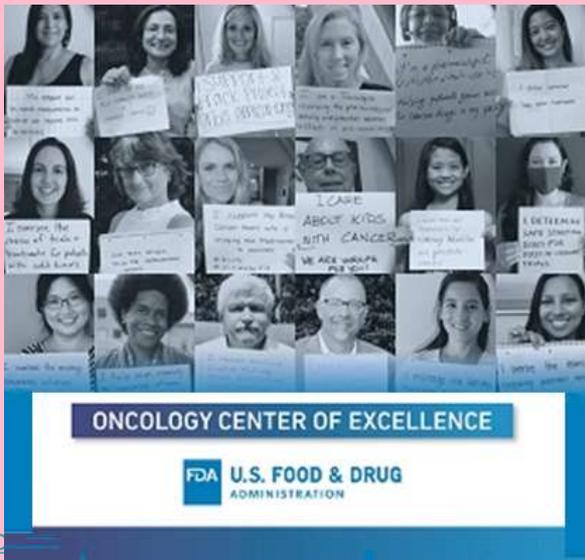
You

Engage



Pharmaceutical Innovator

We



Scientists



Oncologists
Nurses
Pharmacists



Cancer Patient
Advocates

Engage



- With colleagues (oncology subspecialists and FIH clinical trialists)
- **FDA Oncology: AID Meetings, OREEG Program, Interact Meeting, Pre-IND Meeting**

Summary

- Step up to the plate
- Read Listen Learn
- Consultation
- Engage

*“Research is to see
what everybody
else has seen, and
to think what
nobody else has
thought.” - Albert
Szent-Gyorgyi*

