A Reflection on Today's Seminar's Title

Jeffery L. Summers
Associate Director Translational Sciences
Office of Oncologic Disease
CDER | US FDA

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

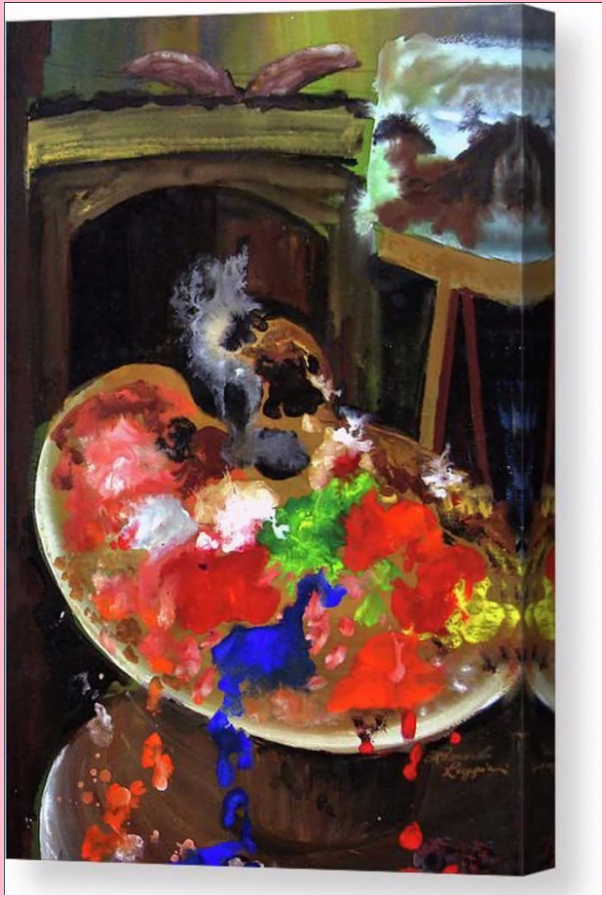
Overview

- 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

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

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
- To help guide you in meeting regulatory standards

The Don’ts ?

- Discovery
- Consultants
- Disclosure
- Financial and Intellectual Property

The Don’ts

- Discovery
- Consultants
- Disclosure
- Financial and Intellectual Property

The Don’ts

- Discovery
- Consultants
- Disclosure
- Financial and Intellectual Property

The Don’ts

- Discovery
- Consultants
- Disclosure
- Financial and Intellectual Property

The Don’ts

- Discovery
- Consultants
- Disclosure
- Financial and Intellectual Property

The One Action for Success
(with a caveat)

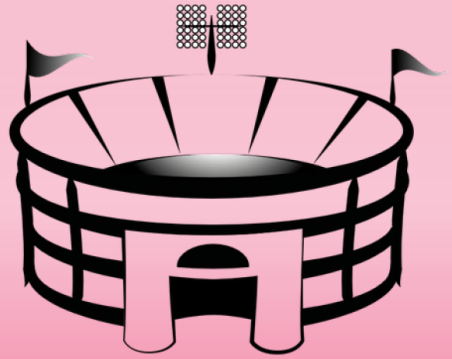
- And the number one action to take is…

Adage of successful drug development

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

Oncology Center of Excellence

Connect With Us!

X: @FDAOncology • Email: FDAOncology@fda.hhs.gov

http -center-
ex

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

FDA Small Business Assistance

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 (MAIT)
800-835-4709 or 240-402-7800
Email: Industry.Biologics@fda.gov

Center for Drug Evaluation and Research (CDER)
Office of Communications
Division of Drug Information (DDI)
Brenda Stodart, PharmD
CDER Small Business and Industry Assistance (CDER SBIA)
866-405-5367 Local: 301-796-6707
Email: CDERSBIA@fda.hhs.gov

Center for Devices and Radiological Health (CDRH)
Office of Communication and Education (OCE)
Division of Industry and Consumer Education (DICE)
Phone: 301-796-7100 or 800-638-2041
Email: DICE@fda.hhs.gov

Accomplishing that task

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

  OCE Project Catalyst Bench to Bedside Chats

Accomplishing that task

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

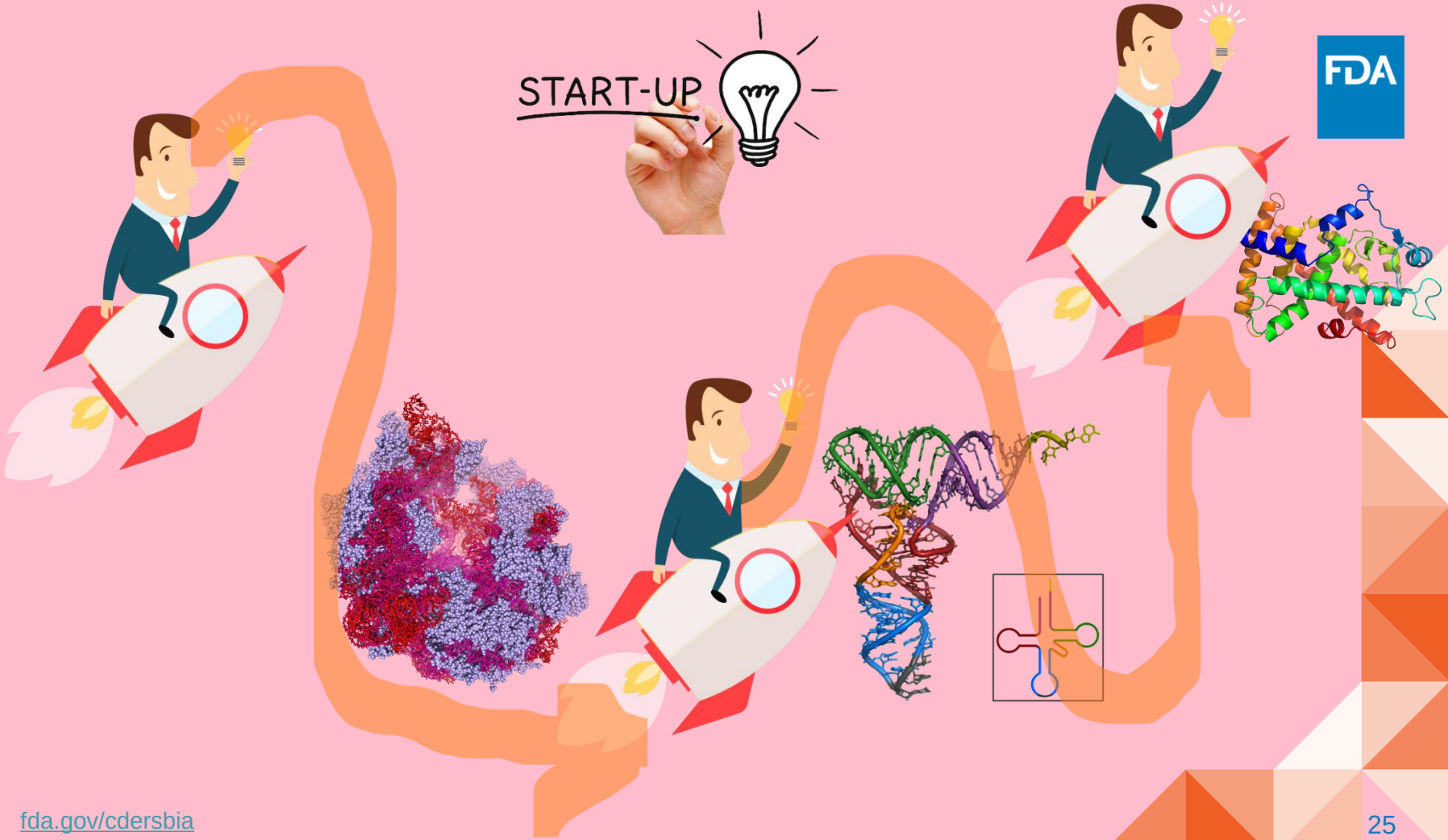
Day Job and then some

- 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

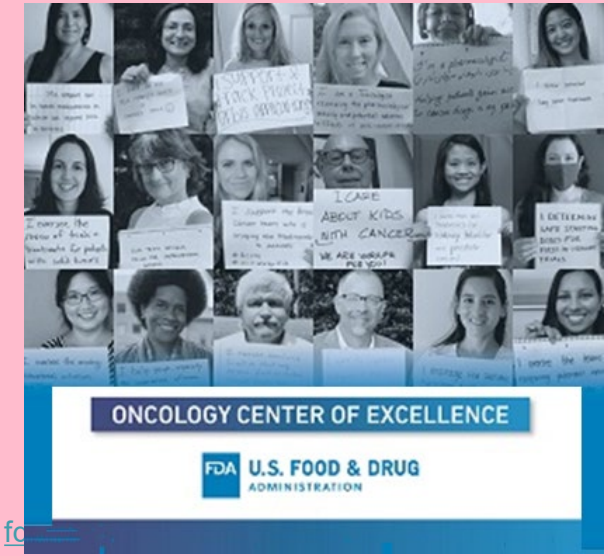
- With colleagues (oncology subspecialists and FIH clinical trialists)
- FDA

Engage

You

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

FDA U.S. FOOD & DRUG ADMINISTRATION

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