

A Reflection on Today's Seminar's Title

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Regulatory Do's and Don'ts: Tips from FDA
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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 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

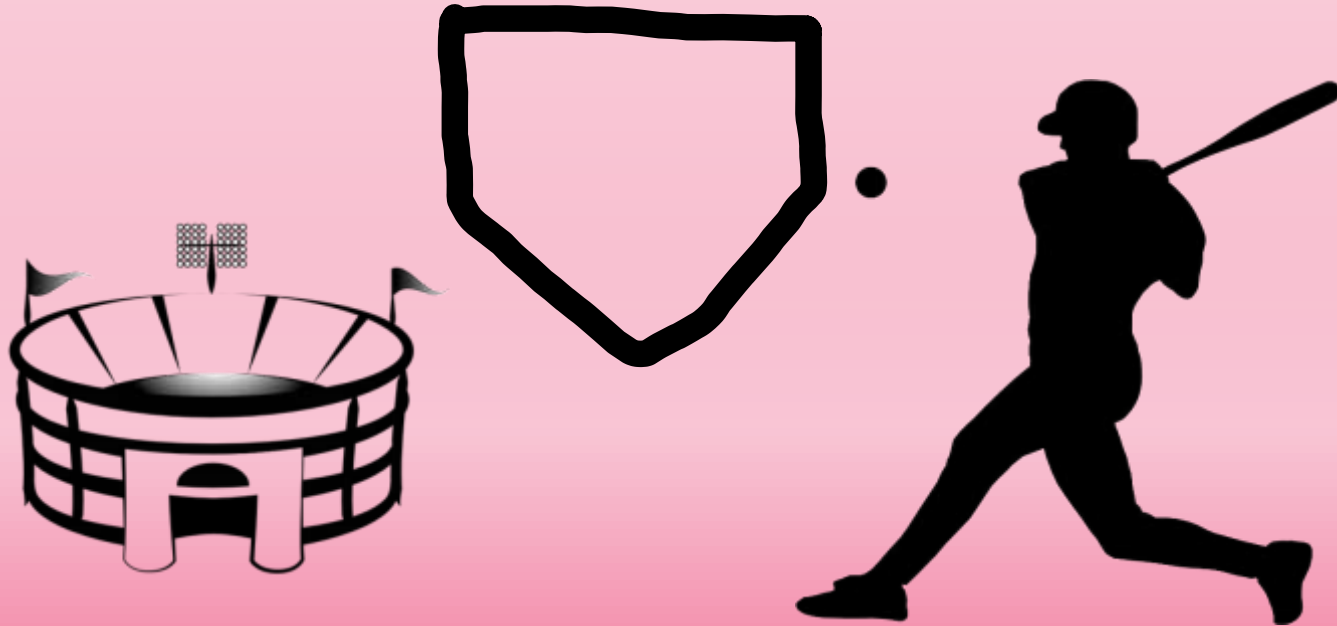
The One Action for Success

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

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

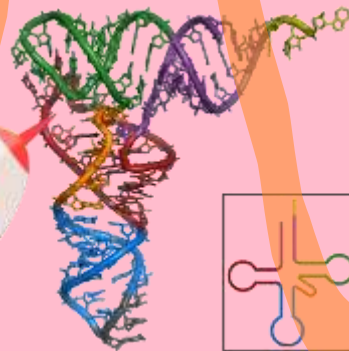
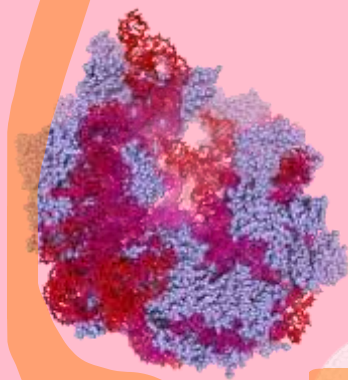
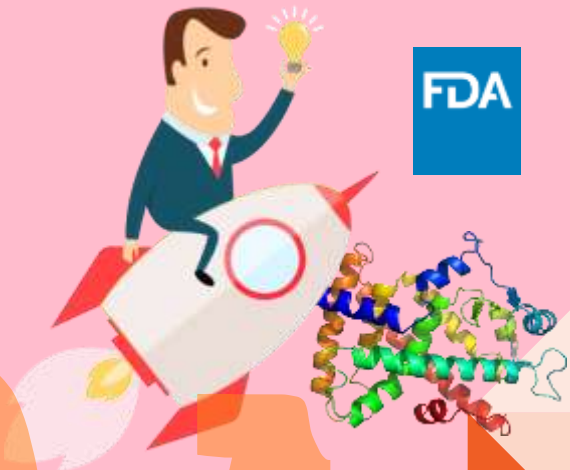
You the audience



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

You



Pharmaceutical Innovator

We

Engage



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*

