
Tips for Your Next eSub

Amanda Yi

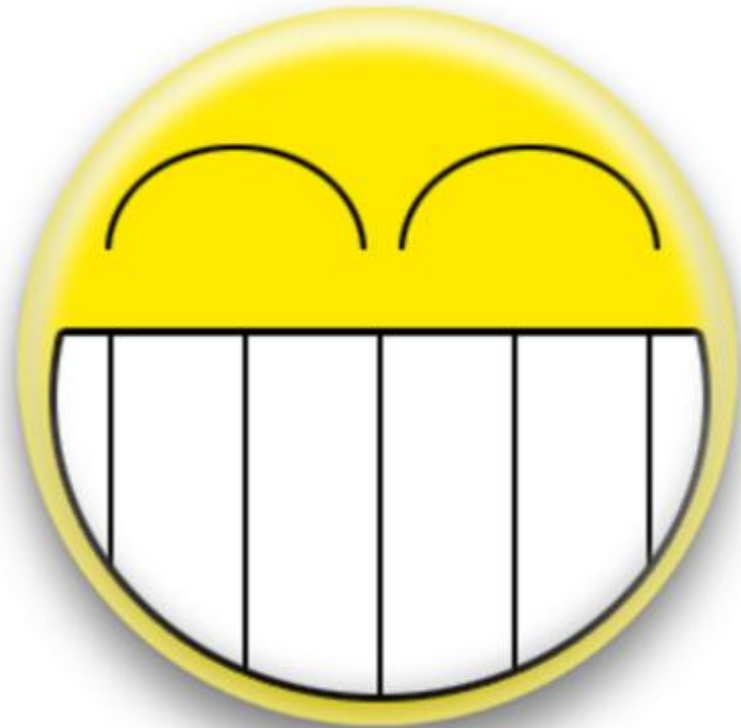
PhUSE SDE, 13th Nov 2015

Shanghai, China

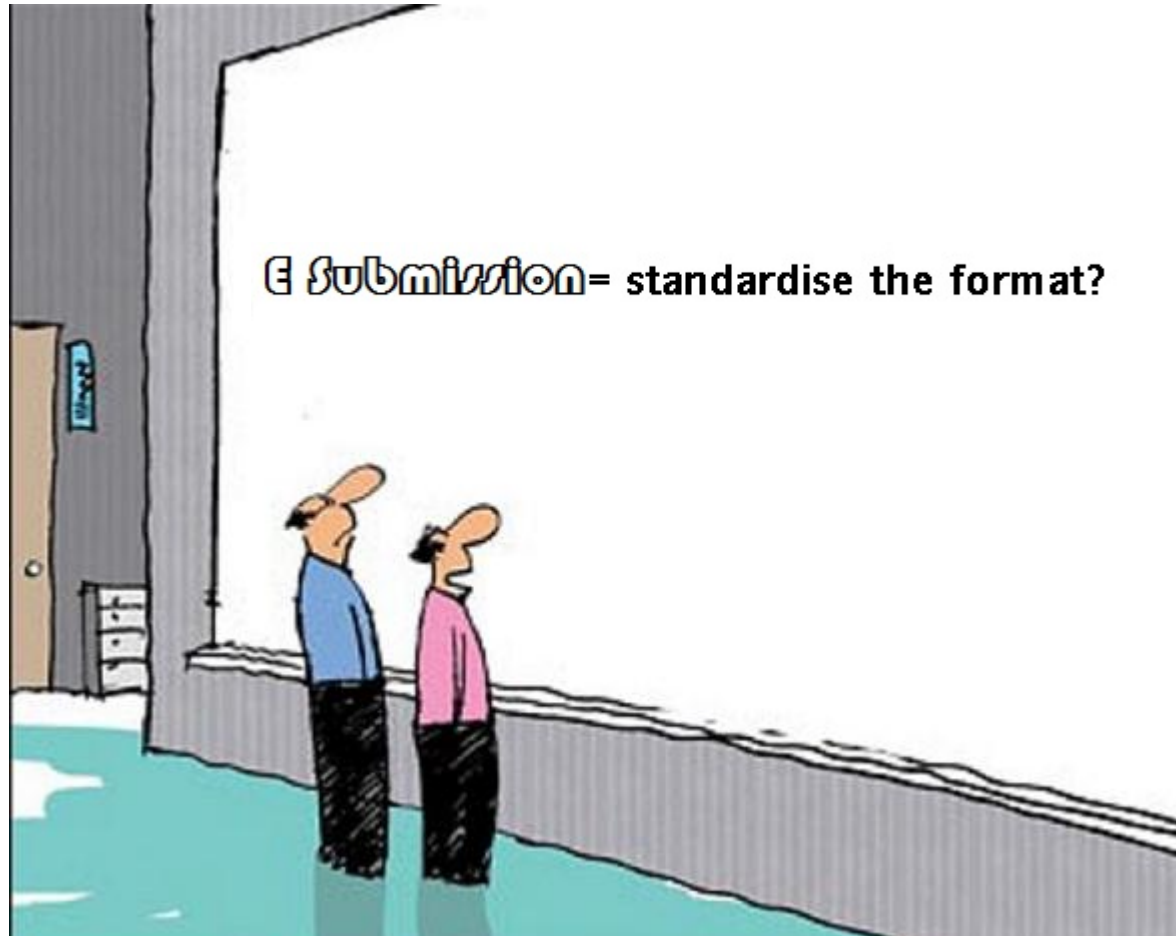


**Everyone Get Ready For Your Next
eSub Task Mentally!**

When I Was Assigned to My 1st eSub Task



When I Calm Down and Started Thinking What eSub Mean To Me?



Without Thinking More, I Quickly Jumped Into The Work...

- Change labels...
- Modify length...
- Compare specs and datasets...
- Rename variables...
- Reorganize derivation comments...
- Find...Replace...in excel



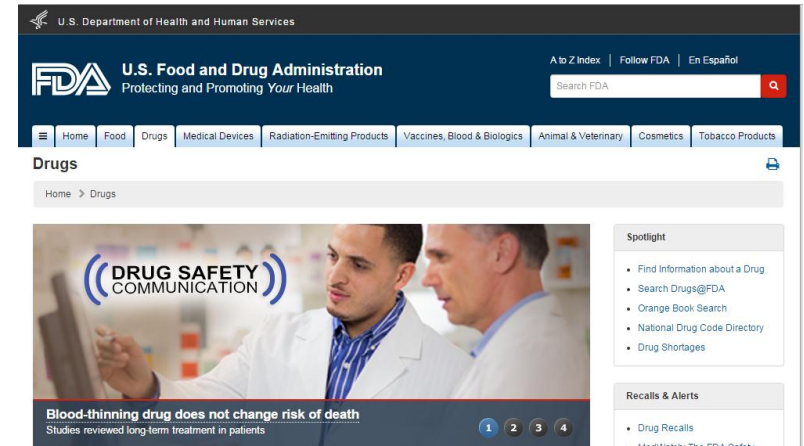
Comments Coming Much More Than Expected



Then I Decided To Do Something...



- Go for some experienced colleagues
- Self reading
- Join the team meeting



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

IND 53728

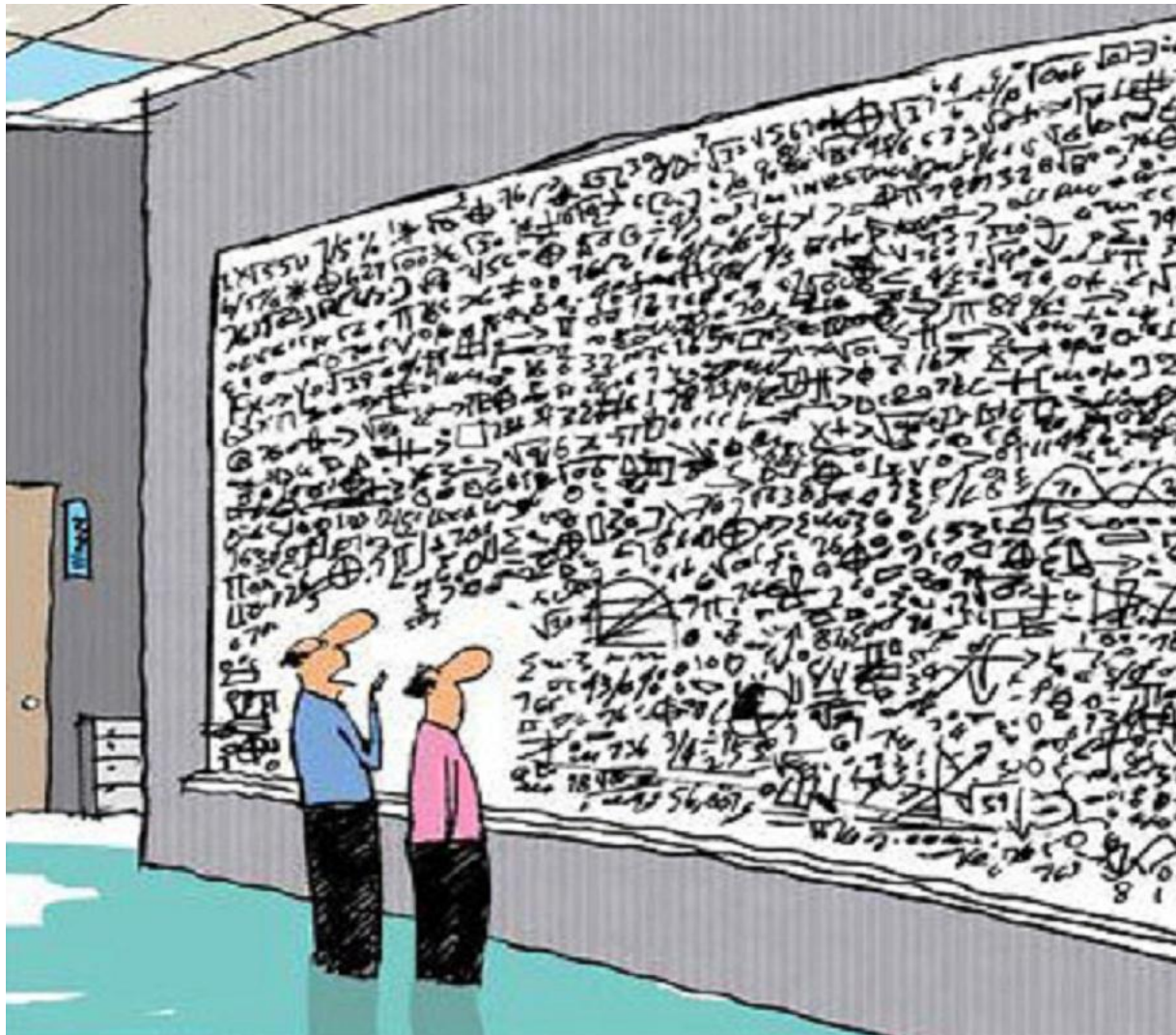
MEETING MINUTES

OSI Pharmaceuticals, LLC
Attention: Donald Raineri, Pharm.D.
Executive Director, Regulatory Affairs
Astellas Pharma Global Development, Inc.
1 Astellas Way
Northbrook, IL, 60062

Dear Dr. Raineri:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for Tarceva (erlotinib).

We also refer to the Type C meeting between representatives of your firm and the FDA on April 14, 2015. The purpose of the meeting was to discuss and reach agreement on the acceptability of



I Felt I Need a Plan to Organize Mountains of Information



- When to submit What?
- Where can I find the study documents?
- Who to contact for data questions?
- Who to contact for agency related questions?
- Any templates available for use?
- Any macros/tools I can use?
- Any reference study I can refer to?
- Any resource to help me if tight timeline?

Responsibilities and Deliverables



	Study SPA Deliverables (Non-CDISC)	eSub SPA Deliverables (Non-CDISC)
Need support from Database Programmer →	Blank CRF	eSub Ready annotated CRF
Legacy Study Template →	Raw Data Specifications	Definel.PDF
	Raw SAS Datasets	Raw SAS Transport Files (.xpt)
Legacy Study Template →	Analysis Data Specifications	Definea.PDF
	Analysis SAS Datasets	Analysis SAS Transport Files (.xpt)
Black box macros; QC programs →	SAS Executable Programs	eSub Ready Programs (.txt)
Available internal template →	Reviewer's Guide, Additional Derivations Specifications doc, Table of Content	eSub Ready Reviewer's Guide

Finally, Job Done Perfectly

Roche

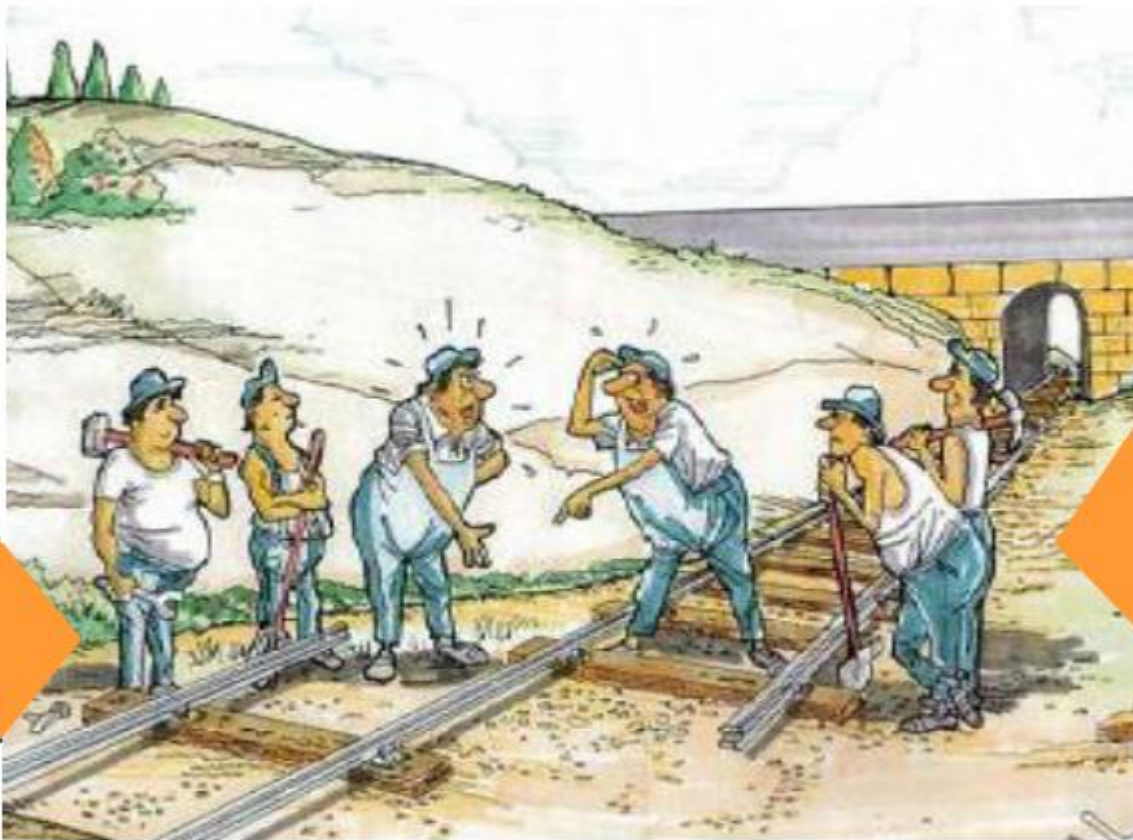


What I learnt are ...

Always Review Agency Correspondence Before You Start The Work



FDA



SPONSOR



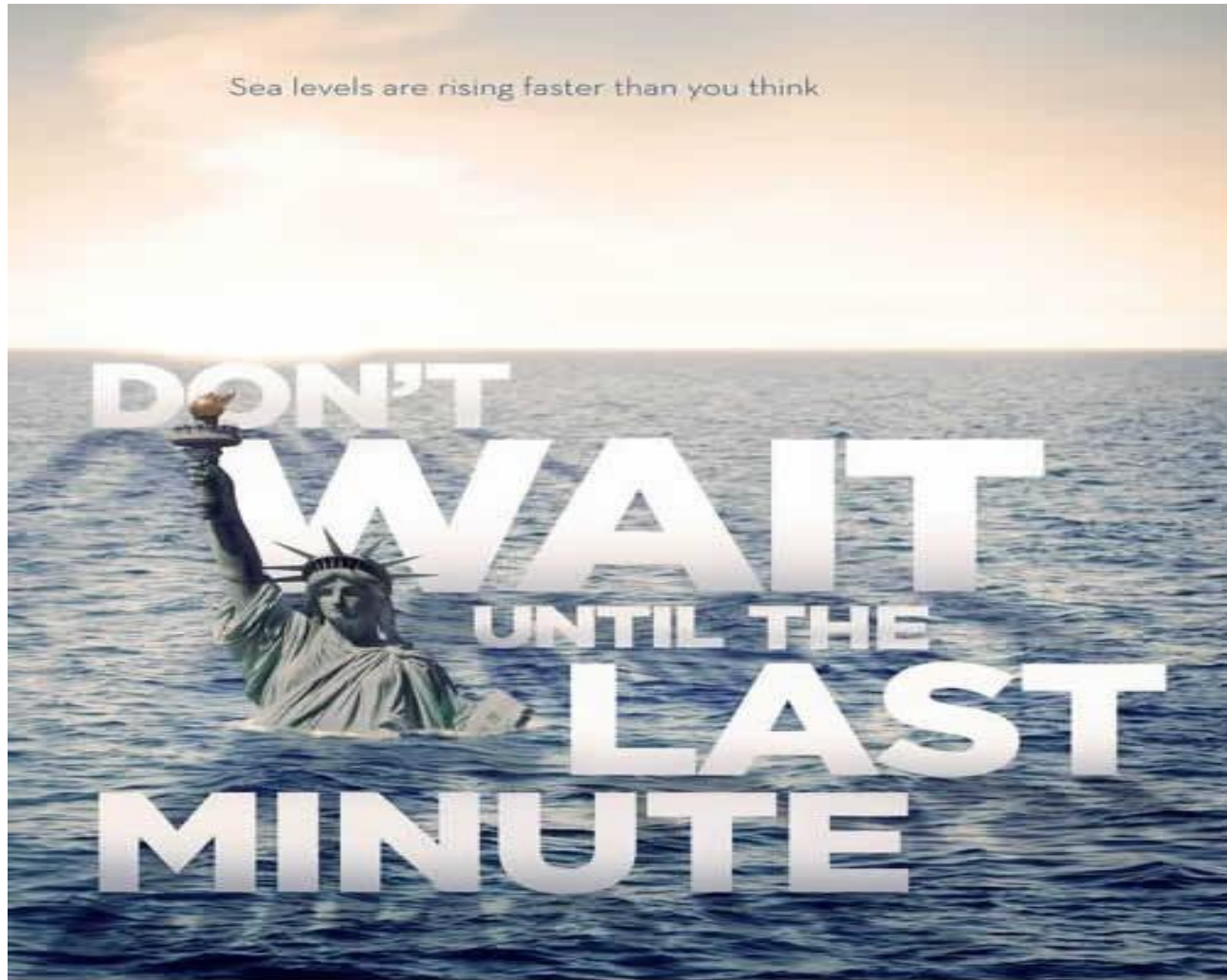
Work Smarter, Not Just Harder

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V.S





Be Flexible Within The Principle



SUCCESS



**WHAT PEOPLE THINK
IT LOOKS LIKE**

SUCCESS



**WHAT IT REALLY
LOOKS LIKE**

Summary - Tips For Your Next eSub

- Always Review Agency Correspondence Before You Start The Work
- Don't Let Too Much Reference Overwhelm You
- Work Smarter, Not Just Harder
- Plan Ahead, Action Ahead
- Be Flexible Within The Principle
- Never Assume Anything

Doing now what patients need next