Enforcing Standards in an Organization: A Practical 6 Step–Approach

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What this presentation is about
A 6-Step Approach

Do Standards exist in your organization? Do your standards comply with CDISC standards and FDA Guidance?

What is the importance of standards (Efficiency, Automation)?

Are there repercussions for not adhering to standards?

Is there a gatekeeper for capturing standards adherence metrics?

Macro adherence utility: for checking the standards macro in project folder

So what? We have standards, tools, and utilities. How effective are they?

Standards in Your Organization

Challenge of having standards in place and consistency of using standards

- Estimates available show that large portions of organizations supporting clinical research use CDISC for database standardization
- (https://www.fda.gov/ForIndustry/FDABasicsforIndustry)

FDA Electronic Submission Gateway (ESG)

FDA ESG 2013-2023 Total Submission Statistics

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Totals
AERS	876,475	1,026,314	1,321,114	1,533,378	1,698,094	2,118,827	2,160,020	2,224,503	2,287,430	2,372,414	1,562,649	19,181,218
CDER	124,232	139,322	159,515	165,932	189,141	221,471	236,584	259,284	283,135	286,917	195,692	2,261,225
CBER	8,412	9,506	11,294	20,278	52,197	56,044	70,900	74,545	716,525	646,370	135,901	1,801,972
CDRH	666,927	812,443	1,478,524	2,032,767	1,921,871	2,247,286	2,774,852	2,960,441	3,774,725	4,851,638	2,797,857	26,319,331
CVM	40,978	44,607	52,601	64,197	70,436	70,682	74,750	86,437	88,216	85,983	68,993	747,880
OC	65,430	68,171	60,943	56,517	71,545	77,353	76,549	73,369	58,843	61,314	31,117	701,151
CTP	1,237	324	734	612	23,984	19,142	3,698	10,563	5,096	4,638	1,151	71,179
ACA	207	195	212	228	218	236	271	288	233	295	308	2,691
GDUFA	2,926	3,547	2,906	1,644	1,600	1,455	1,305	1,249	839	966	816	19,253
CFSAN	4,220	2,756	3,761	3,619	2,661	2,421	2,261	2,160	2,540	2,240	1,757	30,396
HC	324	5,835	9,366	16,497	23,595	26,927	27,302	35,167	40,392	37,634	25,409	248,448
ORA									57	58	20	135
Totals	1,791,368	2,113,020	3,100,970	3,895,669	4,055,342	4,841,844	5,428,492	5,728,006	7,258,031	8,350,467	4,821,670	51,384,879

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Standards Access and Use

Proposal: A dedicated multi-functional Standards Group to support the implementation of clinical data Standards and individual study teams.

Organizations should **maintain a clear location of company standards:**
- OneDrive
- SharePoint Online
- MS Teams

A "**Librarian" :** in charge of maintaining all standards
- CDISC implementation guides
- Controlled Terminology
- Regulatory Guidance
- Other documents

Importance of Standards

1. **Building SDTM/ADaM database**
2. **Programming TLFs**
3. **Creating define documents**
4. **cSDRG/ADRG**
5. **Submission Package (eCRT Packages)**

Pie chart legend:
- Building DB — 36%
- Programming — 20%
- Define — 13%
- cSDRG/ADRG — 12%
- Submission Package — 10%
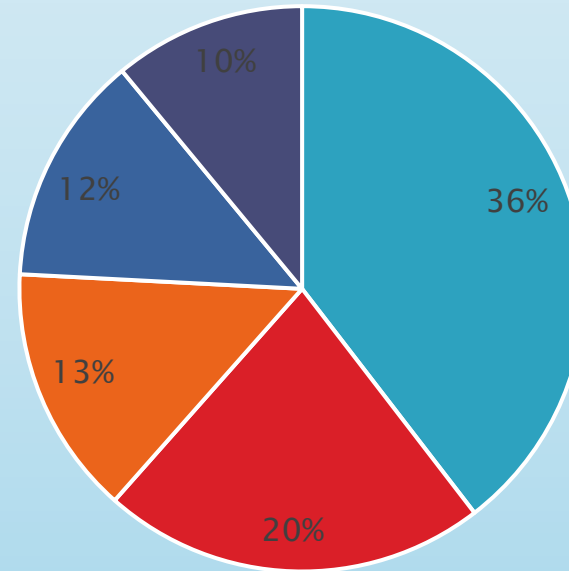
Timelines for your study

Schedule of Events in R&D

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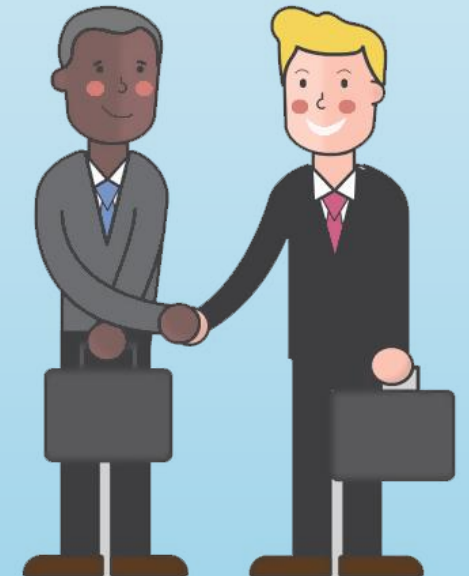# Enforcing Standards

▸ The goal of "enforcement" is not to police project teams

▸ Putting in place a few creative options to encourage adherence to standards

1. Provide metrics on adherence in e-brief or newsletter, or during town hall meeting
2. Possibility for management to tie team and individual performance with the adherence metrics
3. Provide incentives for programmers to continue complying with standards adherence
4. Set up clinics or training programs to show the value of using standards.

Enforcing Standards – "Gatekeeper"

- ➢ Who is the person best suited to be the gatekeeper for standards adherence metrics?
- ➢ The gatekeeper bridges the gap between data acquisition and practical implementation of the standards
- ➢ Programming Managers and Project Leads should serve as the standards gatekeepers
- ➢ Create standards subject matter experts (SMEs) within a team or project that serve as gatekeepers
- ➢ Add gatekeeping responsibilities to the therapeutic area standards team and corporate standards team
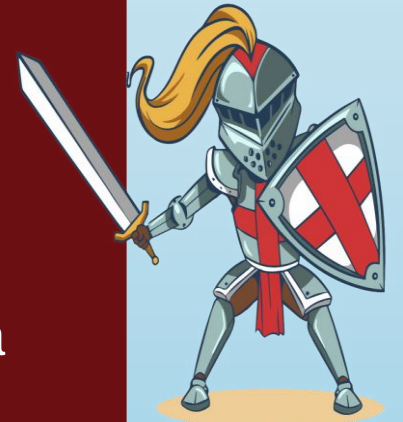
Enforcing Standards – Examples

For example:

1. This team should be able to run utilities to check adherence within studies and projects

2. Monthly report should be generated and shared across the relevant therapeutic areas and project groups

Standards Compliance

In-house developed tools are a great way to assess standards compliance, advantages include:

1. They are usually built to run within your programming platform
2. They can be created with the input of project teams understanding exactly what they need to improve efficiency

Examples of such tools include:

1. Creating utilities that checks within a study folder the standard macros used and generates the compliance report
2. Creating utilities that checks the usage of common variables within the standard domains

Utility Macro

▸ We present a generic utility that can be adopted to complement your organization's platform.

▸ Example utility macro downloadable:

https://statproginc.com/sas-macro-code/

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So What?

- We have standards, tools, and utilities. How effective are they?

- Two approaches are proposed:
  - **Internal validity:**
    - **Using the Likert Scale Questionnaire Survey**
  - **Measuring reliability:**
    - The idea here is to show that if a standard is reliable, it is more likely to be effective.

Using the Likert Scale Method

A Likert Scale is a type of rating scale used to measure attitudes or opinions. With this scale, respondents are asked to rate items on a level of agreement

Strongly agree=5
Agree=4
Neutral=3
Disagree=2
Strongly disagree=1

Agreement: Strongly agree to strongly disagree.
Frequency: Often to never.
Quality: Very good to very bad.
Likelihood: Definitely to never.
Importance: Very important to unimportant.

Four factors should be considered when developing a Likert scale for your tool, utility, or standard:

1. **Define the Focus** e.g., "Standards Effectiveness" or "This Tool"
2. Generate the Likert Scale items
3. Rate the Likert Scale items
4. Administer your Likert Scale test

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Measuring Reliability

The reliability of a standard, system, or tool is a measure of its ability to provide a failure-free operation.

Measuring the failure rate of a standard or tool

Reliability which can be hard to measure

- comparison of two studies under observation, one that uses the tool, and one that does not.
- measure the dependability by comparing a newer version with an older version

- Can be defined as the probability of failure-free software operation

Decision Guide Matrix – Outsourced Studies
"They Mess up Each Time!"

|					
Standards	Missing timelines		Simple systemic errors		High complexity of trial/data/endpoints
	Incomplete delivery		Honest misinterpretation of requirements (SAP/Mockups)		Lack of sponsor oversight/availability
	Poor communication		Lack of consistency		Shift in requirements
Project Facts	Blame-game		Willingness to make corrections and achieve quality		Unrealistic timelines
	Failure to fix findings		Has qualified resources		
	Indifference to escalation				
Project time sensitivity	High	Low	High	Low	High	Low
Decision guide	Fire the vendor	Fire the vendor	Keep the vendor	Keep the vendor	Bring it in house	Keep the vendor
Next Steps	Bring it in house	Outsource again or Bring it in house	Increase sponsor involvement		Tighten up scope. Gain control over details	Increase sponsor involvement
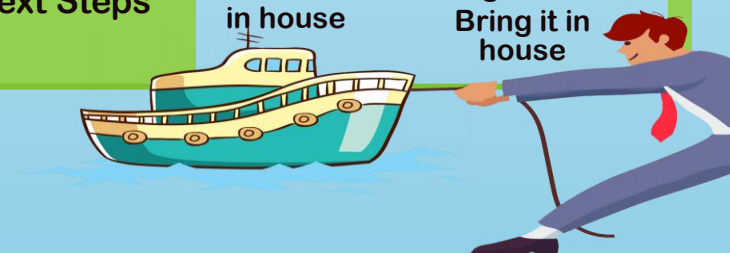
Table Source: Raghunathan, Dilip. PharmaSUG 2019: Avoiding Disaster: Manager's guide on how to rescue a failing outsourced project

Celebrate Your Success in Standards Adherence

- Key ingredient of success is positive morale – cultivate it!

- Team with boots on the ground need to know they are going in the right direction

- Celebrate all small wins!

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Any Questions?