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

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Dr. Priscilla Gathoni, DM, MSc, MBA, GHMGC, is an executive leadership coach, facilitator, author, inspirational and motivational speaker, educator, and voice artist. Dr. Gathoni has delivered inspirational and unforgettable talks at global conferences and community events. As a coach, Dr. Gathoni is a charismatic and energetic coach who uses a non-judgmental approach and proven coaching tools, techniques, and frameworks to enable clients to advance in their thinking, ideas, goals, and aspirations to unlock their true potential. As an educator, Dr. Gathoni is a data science professor at the University of Maryland Global Campus. Dr. Gathoni is the ACADEMIC CHAIR for the PHARMASUG 2024 CONFERENCE.
What is the importance of standards (Efficiency, Automation)?

Are there repercussions for not adhering to standards?

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

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

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<tr>
<td><strong>Totals</strong></td>
<td><strong>1,791,368</strong></td>
<td><strong>2,113,020</strong></td>
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<td><strong>8,350,467</strong></td>
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</table>
Proposition: 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
The reduction of time spent building the analysis databases

- Creating specifications
- Automate when values are defined the same way

Re-use programs (efficiencies)

- Time spent on reviewing the results from the analysis!
- Create tools that allow standards to be used consistently across TAs

Less resource utilization

- Money-saving venture in the short and long term
Timelines for your study

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

Schedule of Events in R&D

- Building DB: 36%
- Programming: 20%
- Define: 13%
- cSDRG/ADRG: 12%
- Submission Package: 10%
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.
➢ 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
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/
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.

<table>
<thead>
<tr>
<th>Strongly agree=5</th>
<th>Agreement: Strongly agree to strongly disagree.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agree=4</td>
<td>Frequency: Often to never.</td>
</tr>
<tr>
<td>Neutral=3</td>
<td>Quality: Very good to very bad.</td>
</tr>
<tr>
<td>Disagree=2</td>
<td>Likelihood: Definitely to never.</td>
</tr>
<tr>
<td>Strongly disagree=1</td>
<td>Importance: Very important to unimportant.</td>
</tr>
</tbody>
</table>

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**
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:

- 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

Reliability which can be hard to measure:

- Can be defined as the probability of failure-free software operation
### Decision Guide Matrix – Outsourced Studies

**“They Mess up Each Time!”**

<table>
<thead>
<tr>
<th>Standards</th>
<th>Project Facts</th>
<th>Project time sensitivity</th>
<th>Decision guide</th>
<th>Next Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing timelines</td>
<td>Simple systemic errors</td>
<td>High</td>
<td>Fire the vendor</td>
<td>Bring it in house</td>
</tr>
<tr>
<td>Incomplete delivery</td>
<td>Honest misinterpretation of requirements (SAP/Mockups)</td>
<td>Low</td>
<td>Fire the vendor</td>
<td>Outsource again or Bring it in house</td>
</tr>
<tr>
<td>Poor communication</td>
<td>Lack of consistency</td>
<td>High</td>
<td>Keep the vendor</td>
<td>Increase sponsor involvement</td>
</tr>
<tr>
<td>Blame-game</td>
<td>Willingness to make corrections and achieve quality</td>
<td>Low</td>
<td>Keep the vendor</td>
<td></td>
</tr>
<tr>
<td>Failure to fix findings</td>
<td>Has qualified resources</td>
<td>High</td>
<td>Bring it in house</td>
<td>Tighten up scope, Gain control over details</td>
</tr>
<tr>
<td>Indifference to escalation</td>
<td>Unrealistic timelines</td>
<td>Low</td>
<td>Keep the vendor</td>
<td>Increase sponsor involvement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Project time sensitivity</th>
<th>High</th>
<th>Low</th>
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<tr>
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<tr>
<th>Decision guide</th>
<th>Fire the vendor</th>
<th>Fire the vendor</th>
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</thead>
<tbody>
<tr>
<td>Next Steps</td>
<td>Bring it in house</td>
<td>Outsource again or Bring it in house</td>
<td>Increase sponsor involvement</td>
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</tr>
</tbody>
</table>

**Table Source:** Raghunathan, Dilip. PharmaSUG 2019: Avoiding Disaster: Manager’s guide on how to rescue a failing outsourced project
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!
Contact us:

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Any Questions?