Reviewer Coaching: Increasing Efficiency Through Communicating Reviewing Best Practices

LIMA CHUTKAN, PHD, RAC
NOVEMBER 7, 2019

Agenda

- Benefits of reviewer coaching
- Team inventory
- Reviewing systems
- Establishing expectations
- Best practices for reviewing
- Reinforcing expectations
- Comment resolution
- Engaging stakeholders

Benefits of Reviewer Coaching

- Reduces reviewer resources and fatigue
- Reduces timelines, including time spent interpreting comments
- Provides consistency across a company
- Establishes expectations
- Leads to high-quality deliverables

Team Inventory

Evaluating Your Team and Project

- Single document
- Submission
- Size
- Experience
- Composition
  - Ally
  - Internal reviewers
  - External reviewers
- Subteams
  - By function
  - Efficacy/non-efficacy or safety/non-safety
  - Regional
- Existing process
Reviewing Systems

PleaseReview

**PROS**
- Real-time collaboration
- Additional review and reference documents
- Good for large or small groups
- Different roles
- Sub-reviews
- Enforces deadlines
- Comment report
- Audit trail
- Standalone or integrated within document management systems

**CONS**
- Technology
- Reviewer training
- Not suitable for authoring
- *Comment bubbles do not show up
- Formatting may not render
- Unwieldy for large files

SharePoint

**PROS**
- Multiple reviewers
- Enforce deadlines through checking out document
- Good for small or large groups
- Reference documents can be included as separate files within the same folder
- Can be used for authoring

**CONS**
- Track changes should be turned on
- Reviewers can upload multiple documents instead of consolidating within one version
- Risk of losing comments
- Extensive training required

Email

**PROS**
- Good for small number of reviewers
- Suitable for authoring/large-scale changes

**CONS**
- No real-time collaboration
- Version control
- Lost changes after combining documents
- Cannot enforce deadlines

Establishing Expectations

**Content**
- Document(s)
- Studies

**Purpose**
- Submission
- Regulatory request/obligation
- Update/amendment

**Structure**
- Summary of changes
- Study reports and summary documents
- Regions
### Document Drafts

**Model/shell documents**
- Focus primarily on methods sections and structure of results sections.
- Secondary focus is wordsmithing “results”.

**Results documents**
- No comments accepted on methods sections unless factually inaccurate.
- Primary focus is on presentation of results.

**First draft vs second draft**
- Thorough review of first draft.
- Less comments on second draft.

### Reviews

**Reviewers by function by draft**
- Discuss roles by draft (reviewer vs viewer)

**Reviewing system and special circumstances**
- Location of reference documents
- How questions will be addressed to the team
- “Alternative text” formatting

**Best practices on commenting**

### Other

**Roundtable expectations**
- Comment adjudication
- Agendas/minutes
- Time limits

**Timelines**

**Special circumstances**

### Best Practices for Reviewing

**Strategic reviewing:** Putting yourself in the shoes of the end user
- Does the document meet its intended purpose?
- Does the document support the strategy?
- Does the document address all the important issues?
- Is any critical information missing?
- Can information be found and interpreted easily?

**Best Practices for Reviewing**

Review according to your expertise area
- Respond to any comments directed to you/your function
- Refrain from open-ended questions
- Make comments specific and actionable/make edits directly
- Review according to the instructions given for the document

---

Best Practices for Commenting

Flag comments as "for discussion" or "major"
Provide any documents referenced in the comment
Delete comments that are no longer needed
Do not comment on formatting or style guide elements
Ensure controversies within function are resolved before commenting

Reinforcing Expectations

Document Writing

Formatting is your friend
- If using PleaseReview, insert comments directly into the document in a consistent format and flag to the team in the instructions
- Consider using different colored highlight/text if alternative text is presented (eg, one paragraph for the US and one paragraph for the EU)
- Flag text that has changed from previous review
- Flag text that does not need to be reviewed (eg, already reviewed methods sections)

Document Writing

Include instructions/guidance to the reviewers on the first page
- Identify any formatting used to aide reviewers
- Flag special circumstances
- Reinforce reviewing rules

Document Writing

Guidance to Reviewing Team
- The format in this SLO is to use the (red) text review which is tender
- Study protocol sections 1-2 written by the lead (if applicable) of the individual countries and as required by the BPharm
- If the protocol study is not in English, send it to the US in English and send the US to the US
- All comments will be reviewed by the reviewer, but only the US is reviewed
- Please do not comment on acknowledgments, references, or any non-essential text

Reviews

Provide instructions for review
- First page of document
- Notification email

Notification email
- Location of review
- Deadline
- Reference/additional review documents
- Roundtable schedule
Comment Resolution

Adjudicating Comments

Build in 1 full day for adjudicating comments
Identify big-ticket items that need cross-functional review
Address comments and communicate resolutions
- Comment from PleaseReview
  - Respond to all comments
  - Document with responses to comments sent to reviewers after review
  - Adding responses during review
  - Encourage reviewers to use comment adjudication day to review responses

Comment Resolution Meeting

Send agenda before meeting
- Bulleted list
- Annotated review document
- Slide deck
Emphasize big-ticket items to be discussed and encourage reviewers to contact you offline for other comments
Reinforce rules
- No discussions longer than 10 minutes
- If no resolution, schedule separate subteam meeting

Engaging Stakeholders

Essential for large, complex, and/or time-sensitive projects
Stakeholders
- First step: Identify the stakeholders
  - Usually not early reviewers
Presenting to stakeholders
- Emphasize how the guidelines proposed serve the project by reducing time and resources
- Provide high-level proposals; save the details for the team
- Ask for their support in enforcing best practices