The Role of the Medical Writer in Study Protocol Development

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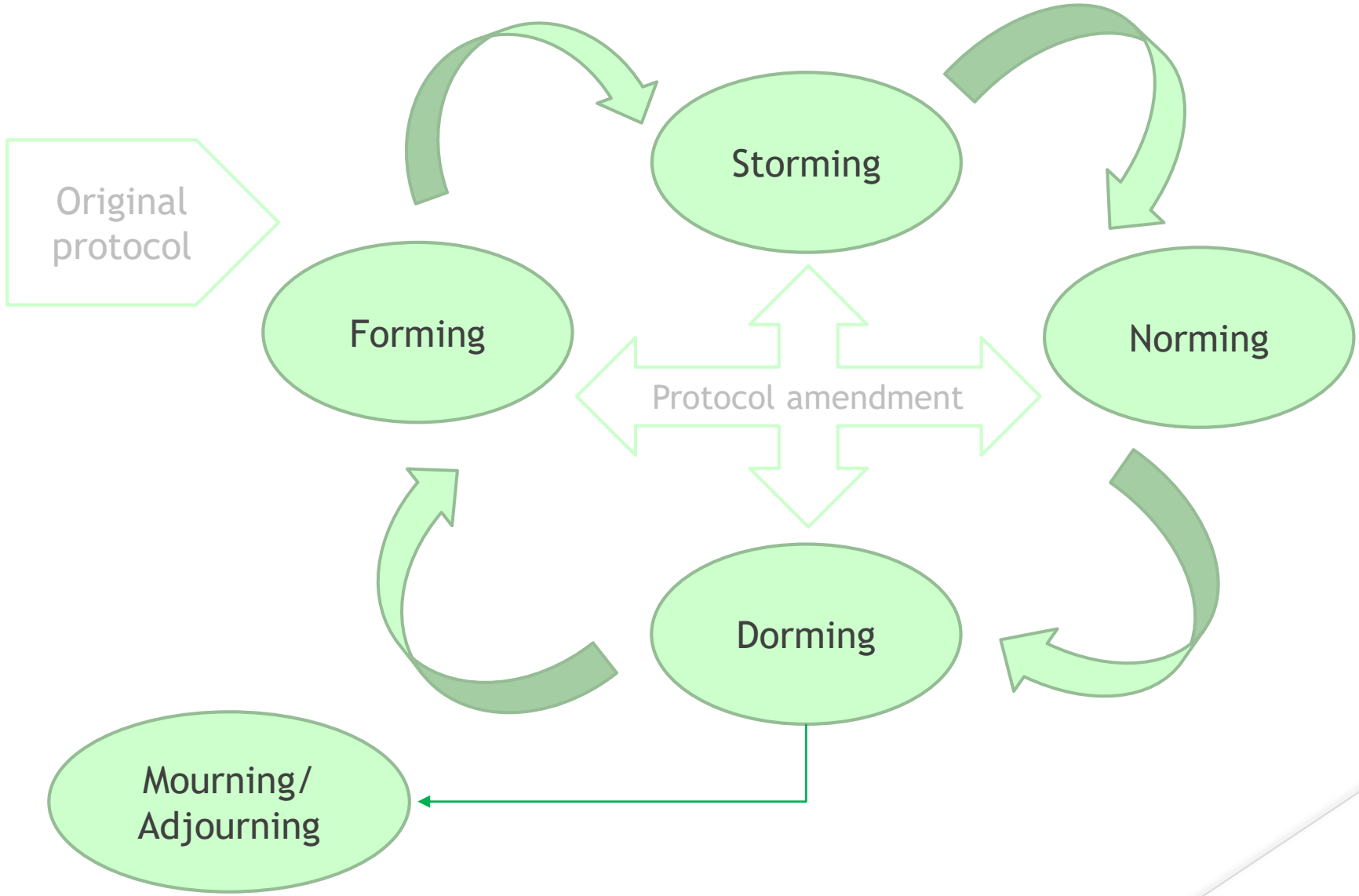
Polling Question

- Who has been a medical writer for more than 5 years? And less?
- Who has worked on protocols?
  - Original protocols
  - Amendments
- Who has worked at a company where another function other than MW handled protocols?

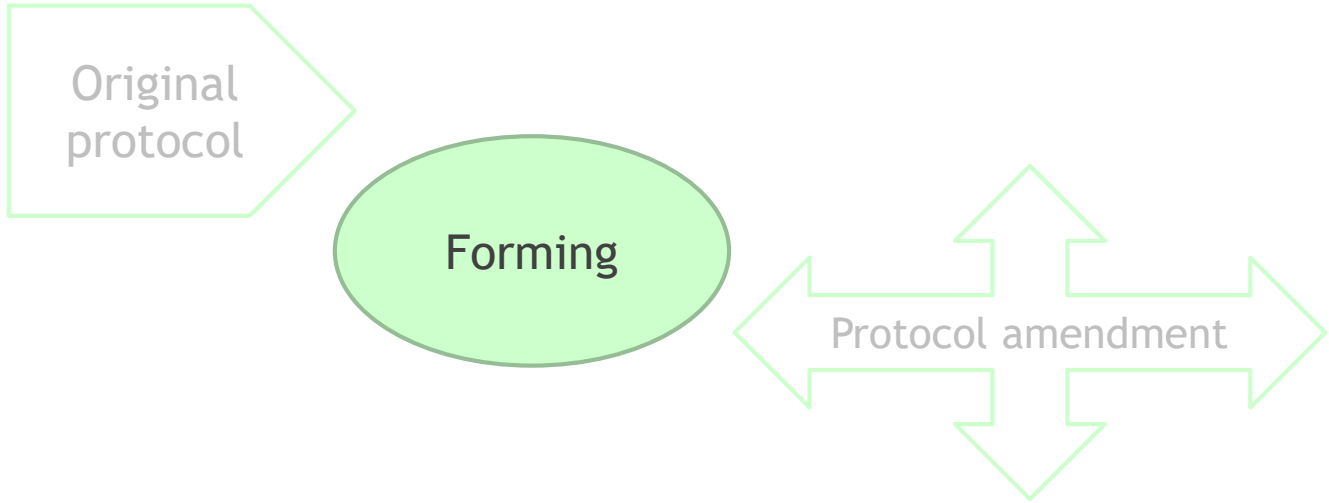
Goals of the Roundtable

- To explore factors or context that may contribute to the success of using medical writing for protocol development at one company and the failure of such an approach at a different company
- To discuss the position of protocol writing within the lifecycle of a clinical trial and of a clinical trial team
- To identify the clinical trial team gaps medical writing may fill during protocol development
- To gather the roundtable participants' collective experience on how a medical writer can be successful in the dynamic environment in which protocol writing often takes place

Tuckman's Theory and Protocol Development

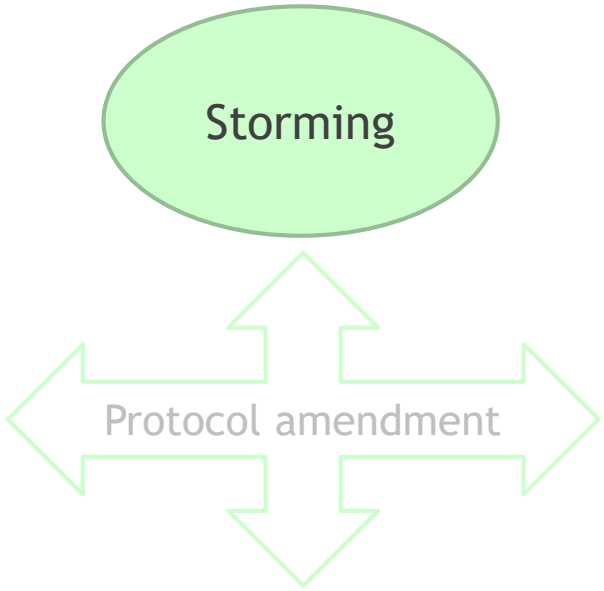


“Forming” and the Original Protocol



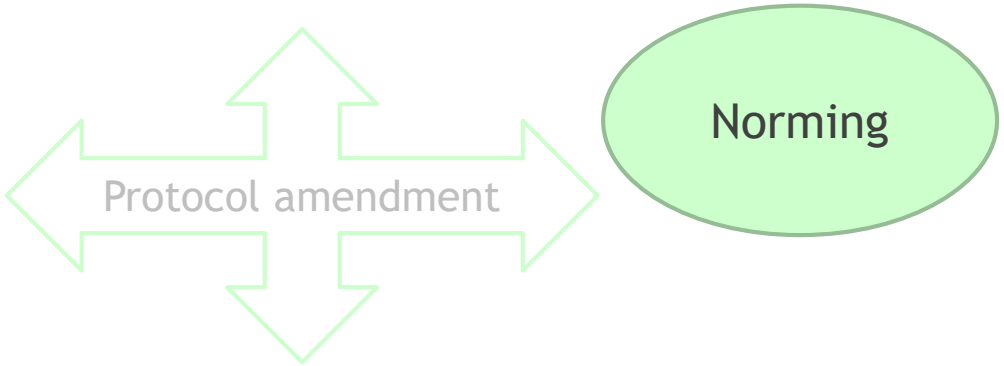
- MW can implement processes that set the stage for the next phases of document and team development and advance quality initiatives
- While the team personalities and nature of their feedback on the study design may be dynamic, the document development process can be somewhat predictable and orderly if well outlined at the onset
- MW can serve as a bridge to ancillary documents such as IND sections and IB that may need to be aligned with protocol at various checkpoints
- For amendments happening due to agency feedback, MW can play integral role in rapid response team

“Storming” and Protocol Amendments



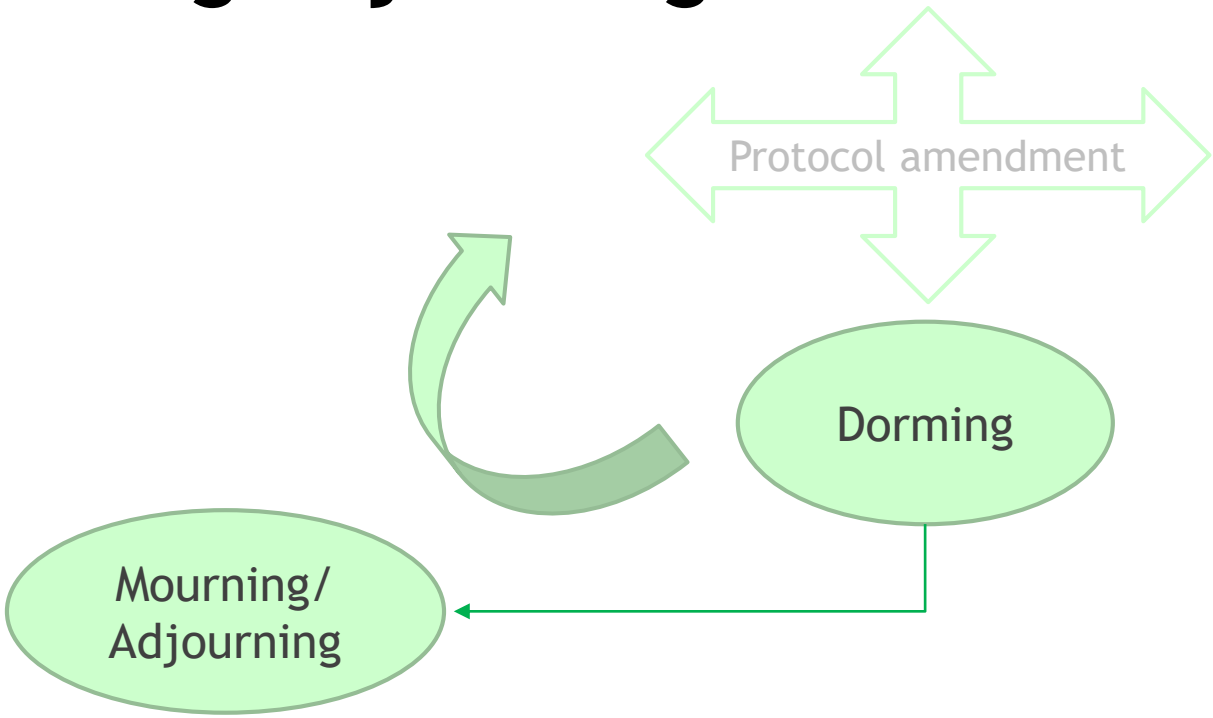
- Time to flex your MW EQ!
- Give psychological wins: updates on progress, a nod to certain groups’ performance in a milestone email, thank reviewers for participating in your meetings
- Continue to build trust by demonstrating command of the amendment content and process; proactively identify and fill gaps
- Bring team together for roundtable and for consensus meetings if issues are identified that can’t be resolved during review
- Let the team know you are receptive to feedback

“Norming” and Protocol Amendments



- MW can help maintain the structure around document writing that has ensured the success of the team to date
- MW can keep communication free-flowing to ensure continued success; talk with team members often
- MW will know its team members and will intuit when to delegate and when to fill a gap based on team members’ strengths (fewer gaps to fill/conversations to facilitate)
- Planning across a program or portfolio behind the scenes is critical to ensure that resources are adequate for when the team inevitably raises the bar on their performance and launches into the “performing” phase

Dorming/Mourning/Adjourning and Protocol Amendments



- While many team members transition away from the study or check out, basic regulatory requirements must still be met for the study or End of Study; MW often left to drive these tasks
- If a gap is created by the departure of critical team member(s), MW may have to make his or herself the study's historian and gather bits of knowledge wherever they can be found
- This stage may also be applicable to teams working on any inherited (or outgoing) legacy study documentation

Tips for Success

- Have a kickoff meeting, whether for original protocol or amendment; outline and get consensus on the following:
  - Roles and responsibilities
  - Expectations for good authoring/review behaviors, including:
    - Commenting etiquette
    - Tips and tricks for review tools (eg, SharePoint, PleaseReview, Adobe Live Review, etc.); be honest about what review tools can or cannot accomplish
    - Review of the shell (concept/synopsis) versus whole document
    - Any review tools or SOPs the reviewers should use (eg, checklists)
  - Document timelines, from start to finish (have preliminary meetings if needed to get consensus on what you will present)

Tips for Success

- Have various checkpoints along the process to collect feedback and check in with authors/reviewers
- Know the process and identify/mitigate risks (eg, protocol does not pass PRC and has to have changes/be sent back to PRC before finalization; CRO needs to give feedback, so plan for it)
- Have an organized roundtable—block off time to vet comments and make slides or sort a comment log for what the whole team needs to weigh in on
  - Use best practices for meetings; state the purpose of the meeting, have an agenda/comments list to guide the meeting, circulate minutes, discuss next steps, etc.
- Have a lessons-learned meeting or collect e-feedback
- Be flexible where you can, be firm where you can't
- Get to know ancillary documentation, even if you aren't responsible for it (eg, ICF, pharmacy manual) to anticipate impact of changes requested by reviewers/authoring team