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White Paper

Can technology tools improve the protocol-writing process?

A Proof of Concept Study by Ascension Healthcare System

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EXECUTIVE SUMMARY

Research protocols are critical documents in the development of clinical trials, including observational studies and social/behavioral/educational studies. The quality of the protocol impacts not only the conduct and outcome of a study, but also the amount of time and resources it takes to gain scientific and IRB approval for the study.

Investigators need to organize and refine their research questions, and put them in writing together with the study rationale, study design, study procedures and ensure regulatory requirements are met. Today, the vast majority of institutions use Microsoft Word protocol templates as the tool to guide investigators' protocol-writing activities. However, this cumbersome proposal tool leaves researchers mired in administrative details all the while assuming their proposals are complete and of acceptable quality when they are, in fact, lacking.

Protocol Builder, a protocol-writing technology developed by BRANY, was developed to rectify these issues. Ascension Health Systems put this technology to the test in a proof of concept study that validated the benefits of using technology to help investigators write protocols versus traditional Microsoft Word templates.

INTRODUCTION

In an innovation proof of concept pilot undertaken by **Ascension Health Information Services** in February/March of 2018, a head to head comparison of Protocol Builder vs traditional Word templates was performed to understand how a new tool could impact the following areas of concern raised when using Word in protocol writing:

Process Improvement

- Word templates require significant preliminary and final formatting/editing on a case-by-case basis for content and substance based upon study type
- Potential for multiple versions extending the collaborative writing process
- Citation management requires multiple resources

Process Integrity

- Word lacks central source for access to current protocol version for collaborative writing and editing
- Word template meets minimum IRB requirements but lacks robust resourcing of information and highest standards of excellence

Error Prevention

- Word General Template requires multiple revisions for study type increasing margin for error
- Lack of citation and reference management requires increased oversite for prevention of error
- Margin of error for omitting critical content is present with general template

Cost & Time

- Significant touchpoints required for review and revision by administrative support personnel translate into
  - Decreased productivity
  - Increased FTE per protocol developed
- Touchpoints Required
  - Formatting document
  - Organization document
  - Resourcing for content
  - Citation management

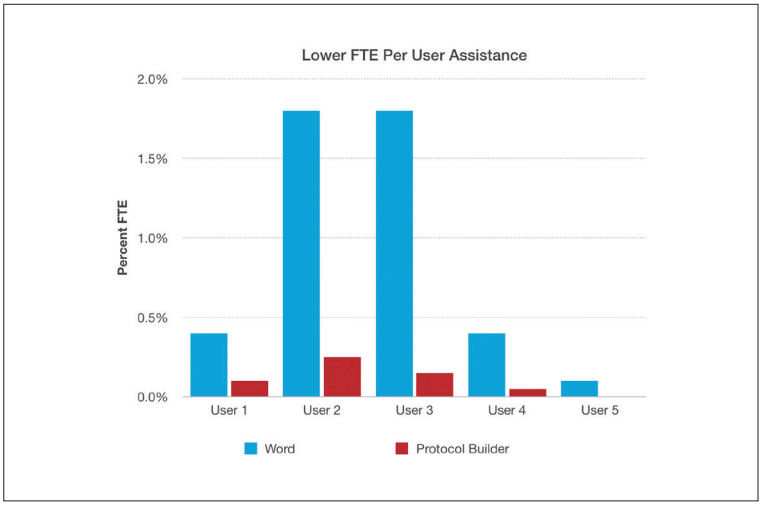
Proof of Concept Evaluation Plan

Five users that ranged from director-level researchers to residents participated in the pilot. The pilot was coordinated by Sara Hollis, the Education & Compliance Coordinator, Saint Thomas Health, Department of Graduate Medical Education (part of Ascension Healthcare System). The pilot was to be measured using the following tools and metrics:

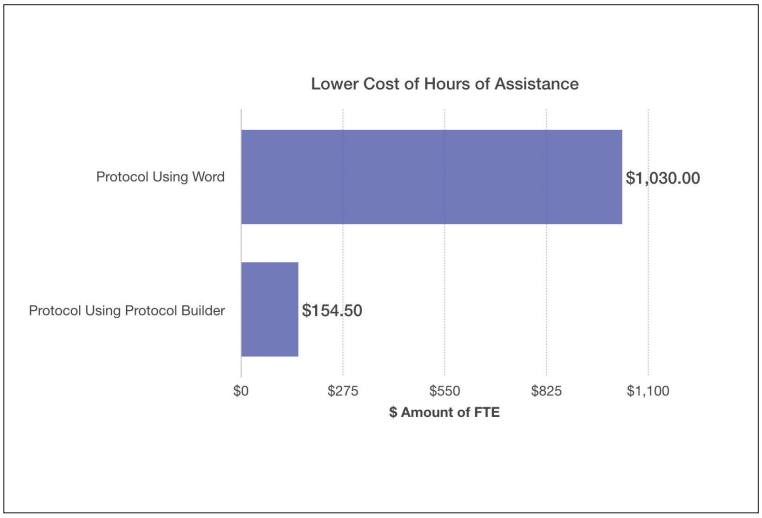
- **Cost & Time:** Assessment of Estimates of Assistance from Administrative Support Personnel
- **Completeness:** Evaluation of protocols written using Word template and Protocol Builder for Gold Standard of completeness/thoroughness
- **User Experience:** Assessment of participant experience of Word template and Protocol Builder

FINDING: PROTOCOL BUILDER REDUCED RESOURCE UTILIZATION

IRB Administrative support personnel manage a significant workload in supporting both industry-sponsored and investigator-initiated research protocols in preparation for IRB review. If IRB support personnel divert their attention from these and handle a myriad of protocol structure-related issues, then this creates unnecessary inefficiencies.

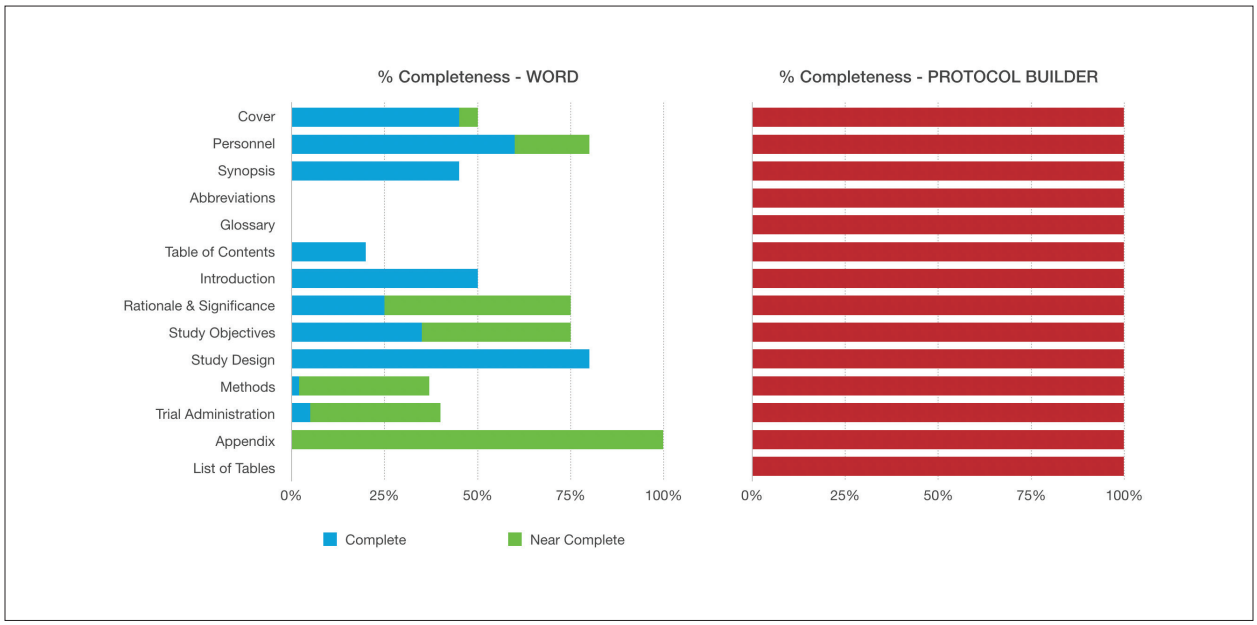


Ascension's proof of concept study found that when comparing two protocols of similar complexity Protocol Builder users required less assistance from administrative support staff than Microsoft Word users, **resulting in an administrative cost decrease of 85%.** Specifically, Protocol Builder reduced the time that administrative support personnel had to devote to formatting, organizing, and citation review of an investigator's submitted protocol.



Users were asked how much help they needed from the coordinator and FTE estimates were developed for a "no help", "some help" and "lots of help" scenarios. In all cases, Protocol Builder required less support than Word. The differential was the greatest for less experienced researchers.

FINDING: PROTOCOL BUILDER ENSURES ACCURACY, COMPLETENESS OF PROTOCOL



Incomplete protocols are a major challenge for HRPP and IRB administration groups. According to a New York University resource, of the "Top 10 Reasons for IRB Rejection" listed, 5 involve missing data: risk statement, right to withdraw, approval letter(s), confidentiality statement, benefits to participant.1 And according to the University of Virginia, submission of the wrong version of a protocol is one of the most common reasons a protocol is rejected by their IRB.[2]

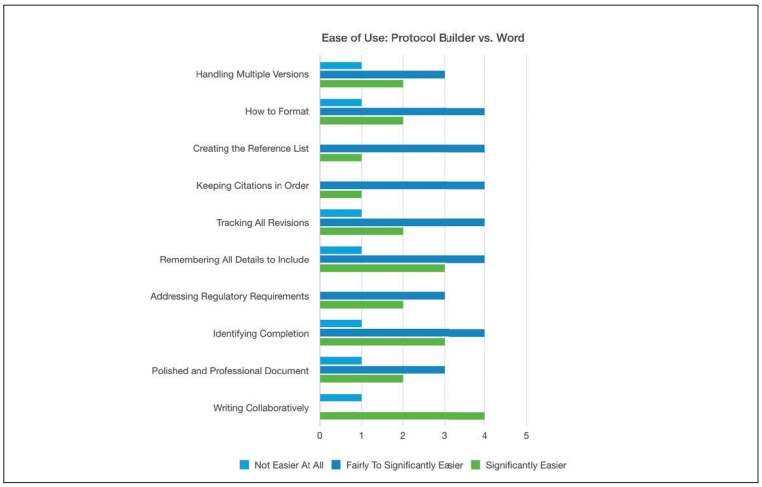
The Ascension Health study first looked at previously written protocols that met minimum requirements for IRB review & approval and assessed the completeness level of all sections:

- 20% - 1 Section Complete
- 80 % - 13 Sections Near Complete or Incomplete

By comparison, **Protocol Builder drove 100% completion of ALL 14 sections.**

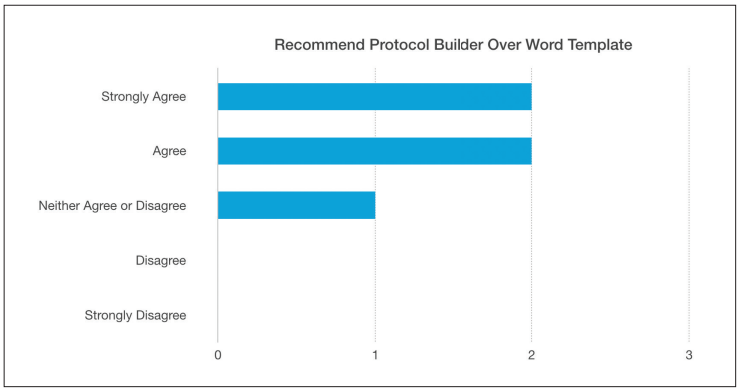
FINDING: PROTOCOL BUILDER IS EASIER TO USE

Investigators, both experienced and beginners, want to focus on their objective: developing an original clinical research idea that could bring value to untold numbers of people (or complete their scholarly activity requirements in the case of residents). If that was not challenging enough, they also need to write a study or trial protocol with the obligatory literature review and meets regulatory requirements.



Shouldn't things be easier if they can be?

In the Ascension Healthcare study, users agreed that **Protocol Builder is "fairly to significantly easier" to use that Microsoft Word** in all areas of protocol writing.



USER FEEDBACK

When Protocol Builder users spoke for themselves they said:

> "Overall, I learned much more about the different types of protocols and the distinctions between them. Protocol Builder provides the correct categories for each template to ensure all that's needed is included... I also really liked the **formatting feature** to produce a professionally formatted document for submission. This reduces the administrative burdens and time needed to format, reformat, and reformat again each time there are changes!"
>
> "It is a step by step process, you are aware of your progress at all times. I liked the quick explanations provided, instructional for each portion, and liked the **collaborative ability.**"
>
> "Definitely **user-friendly** for the unexposed uninitiated!"
>
> "It was **easier to track changes** than in the Word document"
>
> "The program made sure you **completed all sections** so you were not concerned you missed any."

CONCLUSION: AHEAD OF THE CURVE?

While there is an entire universe of software platforms that track IRB submissions and approvals, there have been few, if any, successful initiatives to improve the protocol-writing process. More institutions are upgrading their IRB support systems and will expect, in the near future, to be automated from end to end to gain process and data integration benefits. Technologies like Protocol Builder that are built on modern, flexible platforms allow institutions to take a significant step in that direction while creating time and cost savings for investigators and IRB administration groups.

Protocol Builder® is powered by the Biomedical Research Alliance of New York (BRANY), a leader in providing hospitals and medical schools IRB and clinical research support services.

References:

[1] http://www.nyu.edu/classes/mcdonough/irbrej.htm
[2] http://www.virginia.edu/vpr/irb/hsr/reasons_not_approved.html