

Bookmarking CRFs More Efficiently

Paper EP-096

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Abstract

Introduction

Steps

Results

Conclusions

References

ABSTRACT

Preparing an annotated CRF (aCRF) entails adding PDF bookmarks. Adding bookmarks manually is a time-consuming process. This paper describes how to automate aspects of this process, including the specification of bookmark properties required by the FDA and/or CDISC (namely, nested levels and inherit zoom magnification).

This paper assumes the reader knows how to edit the Windows PATH environment variable and use a Windows command line.

Click Headings Above to
View Content



Next

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INTRODUCTION

The annotated case report form (aCRF) is a required component of the clinical data submission package sent to the FDA. The aCRF requires two sets of bookmarks, by visits and by topic (CRF form).

Manually bookmarking an aCRF can be time-consuming within a PDF editor (such as Adobe Acrobat). Also, if the aCRF is updated, this may require having to add bookmarks again from scratch, as there may not be a clean and simple way to transfer bookmarks from one PDF file to another.

This e-poster outlines a semi-automated method for bookmarking an aCRF. This method can be used even in cases where access to the EDC Study Data Specification is not available.

STEP 1: EXCEL

We start with an Excel spreadsheet, having one row per visit and topic (CRF form), and the following columns:

- VISITSEQ (to specify chronological order of visits)
- VISIT (visit name)
- FORMNAME (CRF form name)
- PAGENUM (page number)

STEP 2: EXCEL to PDFMARK

Using macros in the Appendix of the paper, we can take the bookmark information in the spreadsheet to generate Postscript files that look something like this:

```
[ /PageMode /UseOutlines /Page 1 /View
[/Fit] /DOCVIEW pdfmark
[ /Page 1 /View [/XYZ null null 0] /Title
(Visit) /Count 9 /OUT pdfmark
[ /Page 5 /View [/XYZ null null 0] /Title
(Screening ) /Count 45 /OUT pdfmark
[ /Page 1 /View [/XYZ null null 0] /Title
(Administration of Study Drug ) /OUT
pdfmark
[ /Page 4 /View [/XYZ null null 0] /Title
(Adverse Event ) /OUT pdfmark
...
```

METHOD 3: PDFMARK to PDF

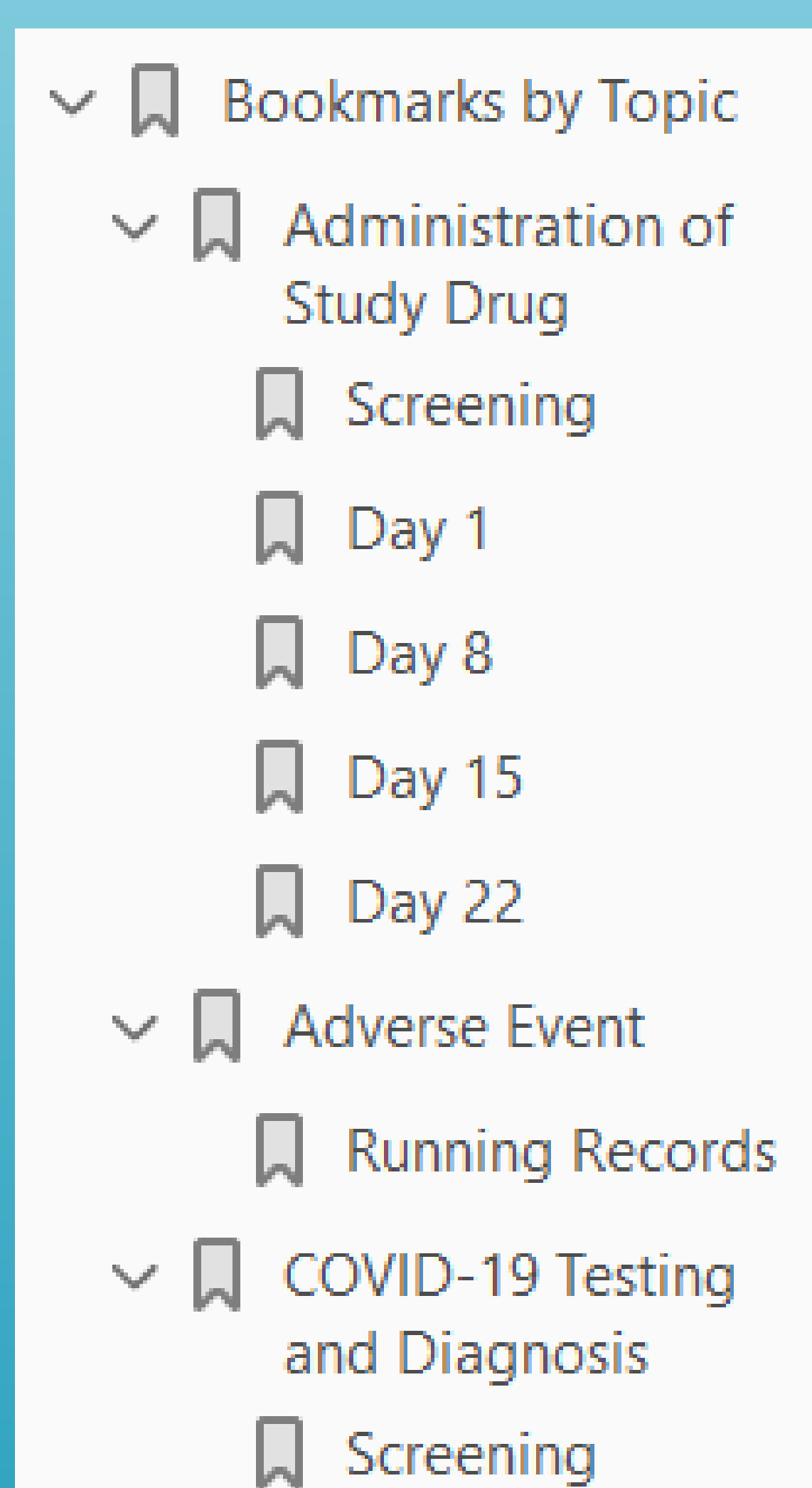
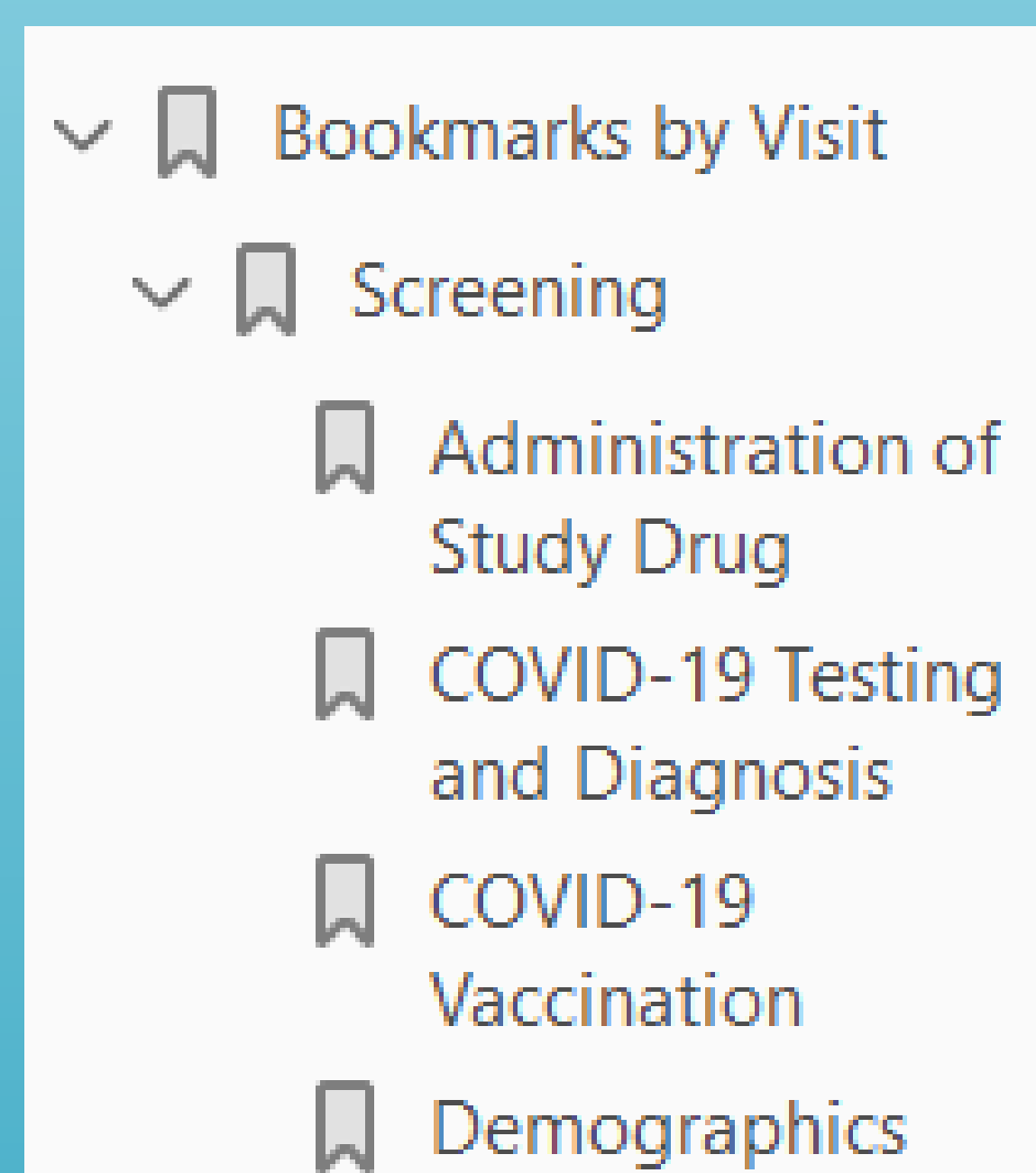
We can then use Ghostscript commands in a Windows Powershell to push the PDFMARK bookmarking data into the aCRF (PDF file).

```
>gswin64c -o tempfile.pdf -
sDEVICE=pdfwrite -
dPDFSETTINGS=/prepress
acrf_without_bookmarks.pdf
bm_by_visit.ps

>gswin64c -o acrf_with_bookmarks.pdf
-sDEVICE=pdfwrite -
dPDFSETTINGS=/prepress tempfile.pdf
bm_by_topic.ps
```

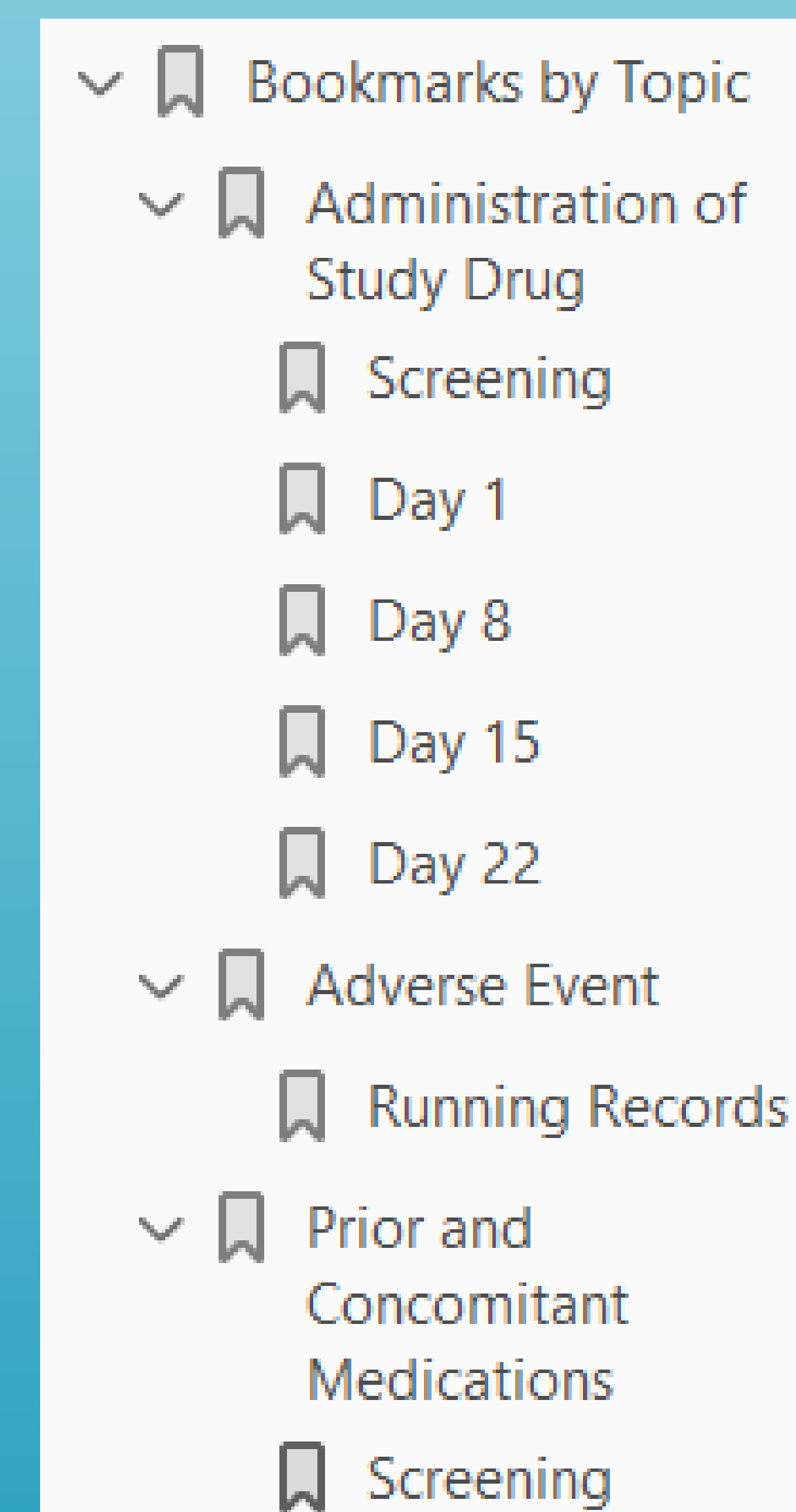
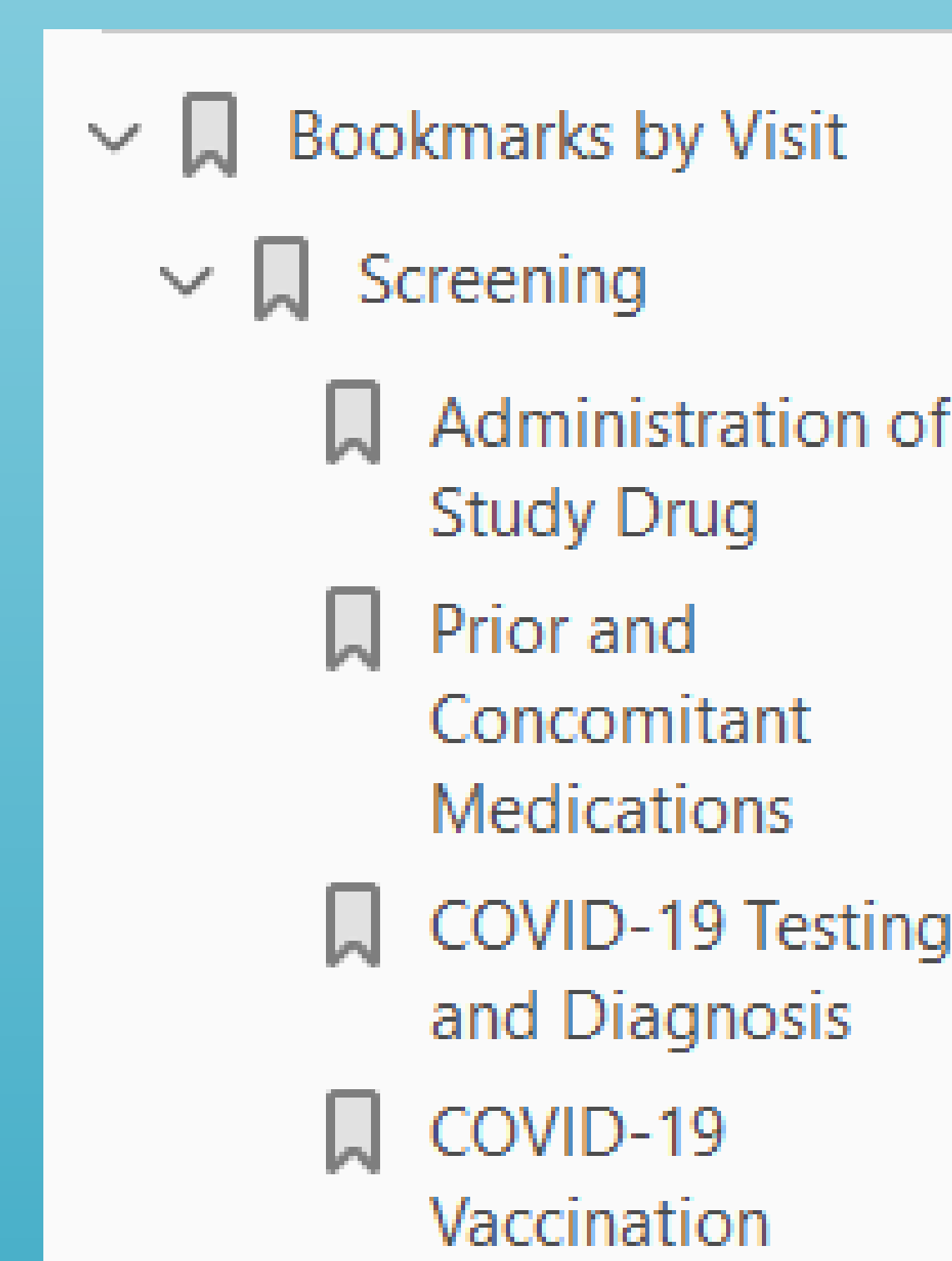
RESULTS 1

You can have the CRF form names appear alphabetically. This is the default setting of the macros provided in the Appendix of this paper.



RESULTS 2

You can opt to have the CRF forms sorted by page number instead.



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CONCLUSIONS

The process presented in this paper can reduce the time spent bookmarking an aCRF. The bookmarking data is prepped in Excel, where it is easier to organize than within the PDF file itself. The macros provided in the Appendix automatically specify nesting levels and inherit zoom, further reducing the manual effort and time required to complete this task.

REFERENCES

CDISC SDS MSG Team. (2021) “Study Data Tabulation Model Metadata Submission Guidelines (SDTM-MSG): Human Clinical Trials.” Version 2.0 (Final), 2021-03-30.

Kent, Chris. (2017) “Adding Bookmarks to PDF Documents with pdfmark.” thechriskent.com

See Paper EP-096 for a complete list of references.

