



42nd
Annual Meeting



Philadelphia 2006

Standards and Successful Document Creation

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Why are we here?

- ISS/ISE placement one of the most frequently asked questions
- ISS/ISE Represent Analysis
 - 5.3.5.3 Reports of analyses of data from more than one study
 - Module 5 provides necessary organization structures through STF
- Module 2 Summaries
 - Critical and Concise Summaries
 - Page count do not define what's acceptable



The Importance of Standards

- FDA Presentation in June of 2002

http://www.fda.gov/cder/regulatory/ersr/2002_0-6_19_standards/index.htm

- Critical if FDA is to modernize the review process
- Critical to building more collaborative review processes
 - caBIG <https://cabig.nci.nih.gov>
- Critical to improving reviewer efficiency and effectiveness through repeatability
- Not limited to Drug/Biologic Review Processes



Practical Document Standards

- Enhances the reviewer's experience
- Decreased inter-application variability
- Decreases reviewer ramp up time
- Allows industry to develop standard templates



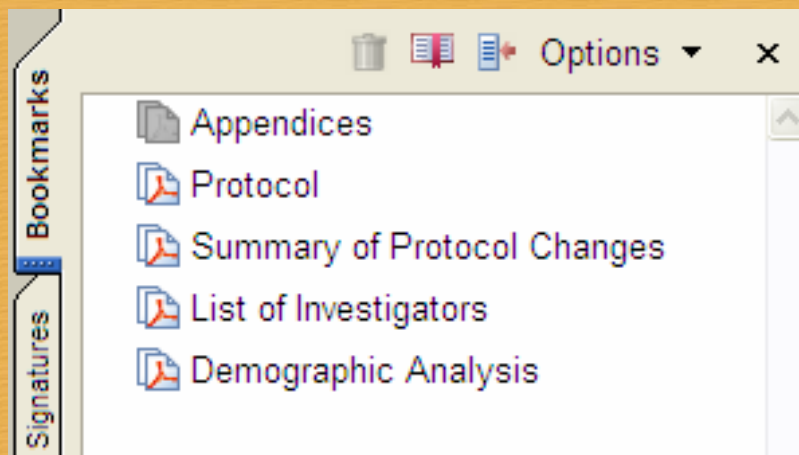
Remember!

- **One of your goals is communication**
 - Clarity improves reviewability
 - Consider application from reviewer's standpoint
 - Create document level Tables of Content with appropriate bookmarks
 - Use clear concise leaf titles

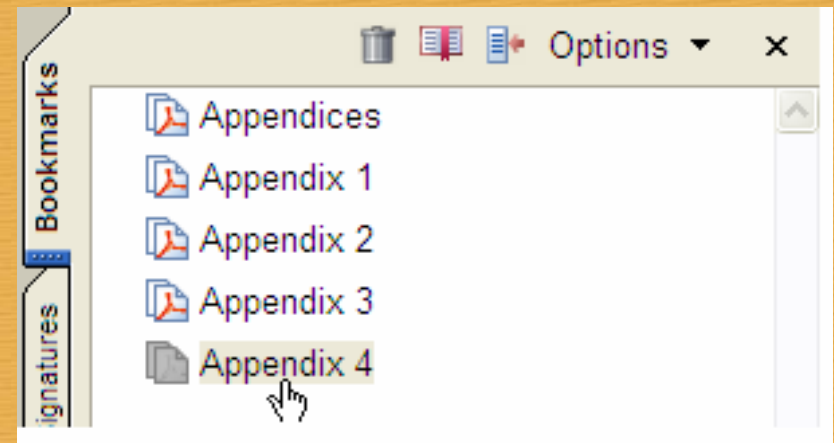


Provide Bookmarks with Intuitive Names

- Good

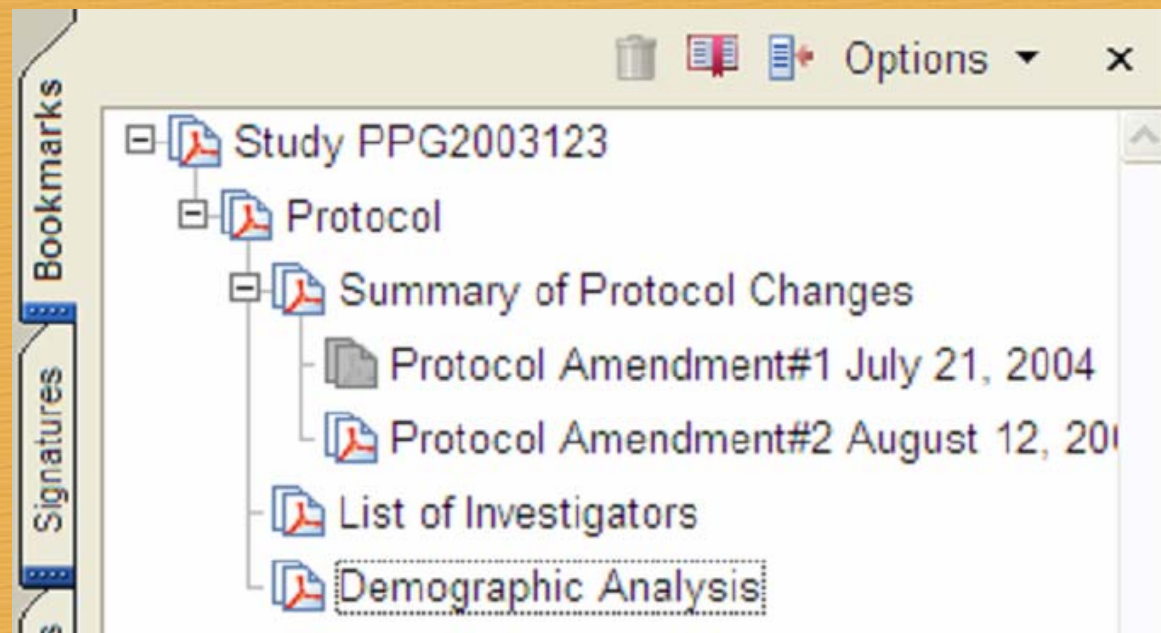


- Bad

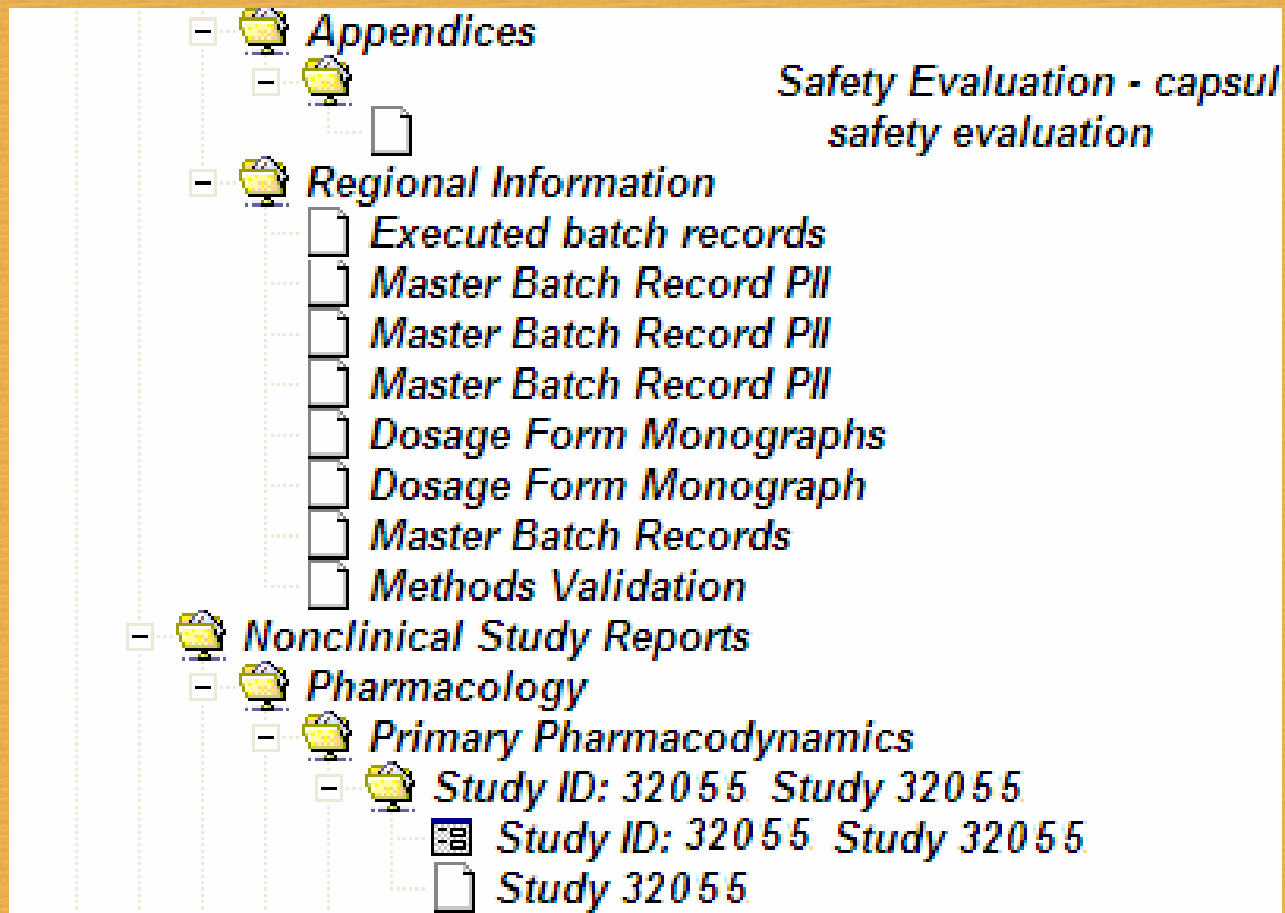


Bookmarks

- Useful to have a bookmarks back to higher levels of the submission



Clear Concise Leaf Titles



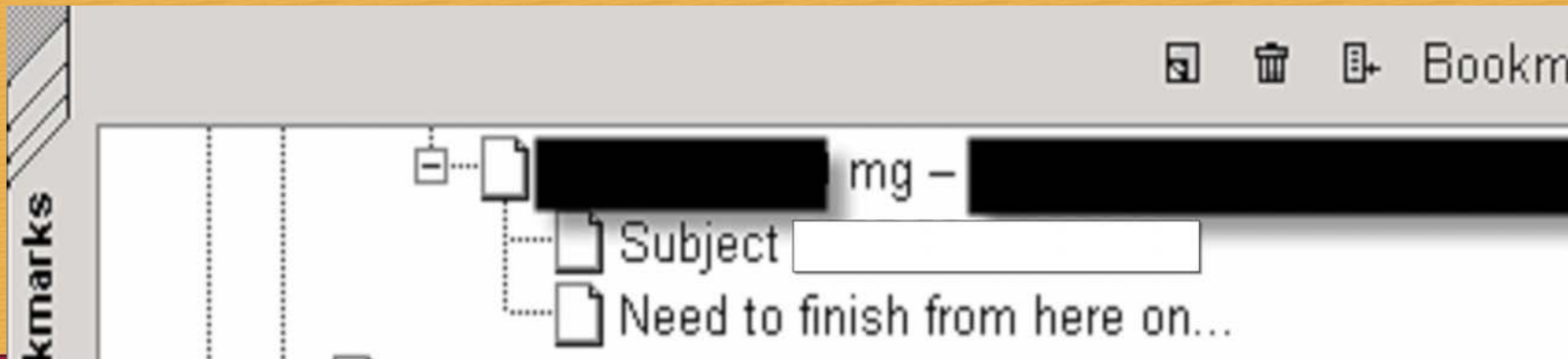
ISS/ISE Experiences

- Documents are varied
 - Application A
 - 2.7.3 70 pages
 - 2.7.4 86 pages
 - Application B
 - 2.7.3 697 pages
 - 2.7.4 904 pages
 - Application C
 - 2.7.3 3,519 pages
 - 2,7,4 10,469 pages



Most Egregious Examples

- Page count in excess of 20,000
- Scanned document
- No table of contents
- Bad bookmarks



Contact Information

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