Ensuring a Effective Submission

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Remember!

- One of your goals is communication
  - Clarity improves reviewability
  - Consider application from reviewer's standpoint
    - What would you want to know
  - Create document level Tables of Content with appropriate bookmarks
  - Use meaningful file names
  - Use clear concise leaf titles

Have a Pre-Meeting to Discuss the Electronic Submission

- Schedule prior to assembling application, e.g., 6 to 12 months prior to submission of the application
- Discuss data, datasets, format

Contact Electronic Submission Coordinator

- Initiate contact prior to assembling application
- Arrange participation in eCTD Pilot
- Clarify Guidance questions
- Contact addresses:

  cder-edata@cder.fda.gov

  esub@cder.fda.gov

Submitting Electronic Submissions

- CDER:
  - ALL electronic submissions for original applications, supplements, and amendments, must be sent to the Central Document Room
- CDER: OGD
  - All electronic submission to the OGD document room
- Send only ONE copy of the electronic submission
- Use the correct electronic media and choose type appropriate to size of submission

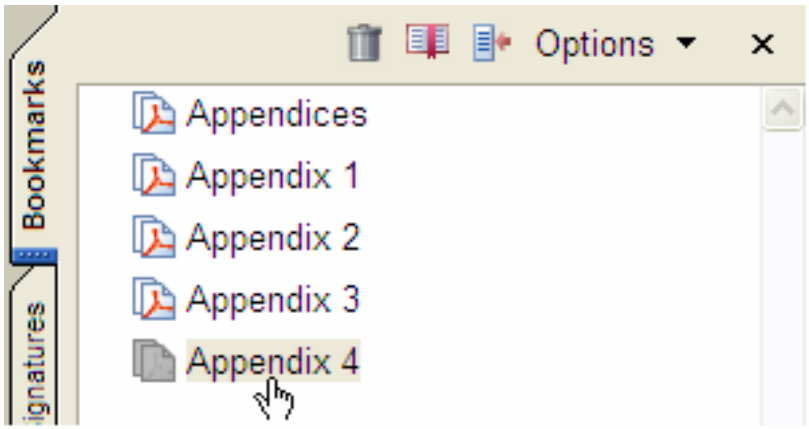
Submitting Electronic Submissions

Continued…

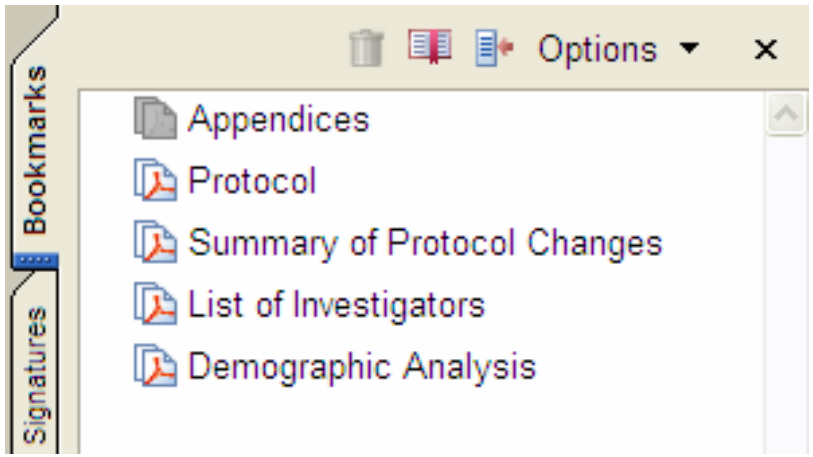
- eCTD
  - Should not include any paper
    - If Part 11 compliant electronic signatures are available otherwise only documents requiring original signatures
  - Include all required eCTD files
  - Include all required forms, letters, and certifications
  - Be sure ALL files submitted are referenced in XML backbone
  - Do not use Node extensions

Provide Bookmarks with Intuitive Names

- Bad

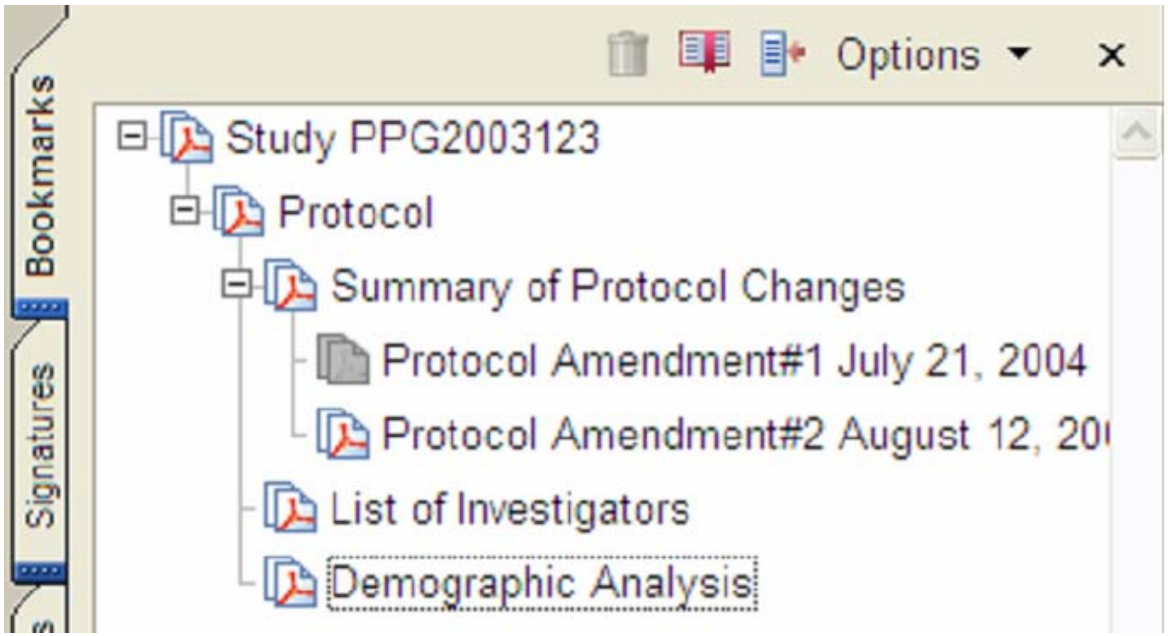


- Good



Bookmarks

- Useful to have a bookmarks arranged hierarchically



Provide Hypertext Links

- They enhance navigation and improve reviewability.
- When to provide them?
  - Anytime the text refers to a reference (table, figure, etc.) that is not on the same page.

References

- CDER Contact for information on eCTD submissions

  esub@cder.fda.gov
- CDER Contact for information on SDTM submissions

  cder-edata@cder.fda.gov
- Electronic Regulatory Submissions and Review website

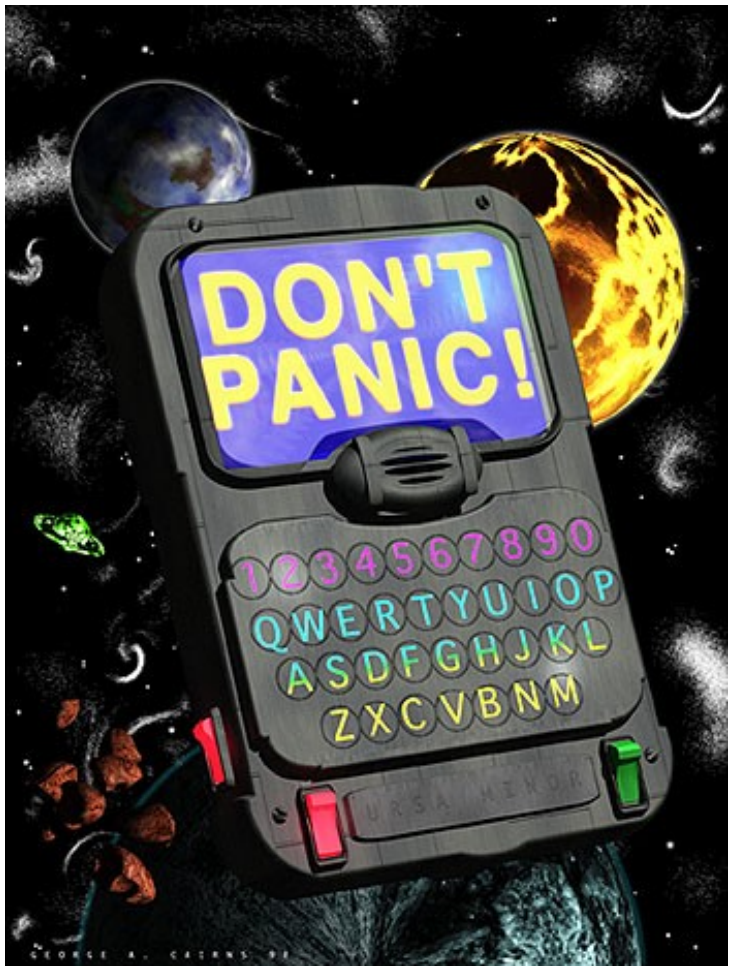
  http://www.fda.gov/cder/regulatory/ersr/default.htm
- International Conference on Harmonization

  http://www.ich.org

Remember what we said earlier about following the rules…

Well, if you don’t follow the rules…

But seriously though…



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