CTD Experience

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CTD Experience

- European study reports cross-referencing
- TPD requires more actual source documents
  - e.g. specifications signed by QA
- Challenges in study reports
  - Interpretation of guidelines by CROs
  - Unclear if drafts should be followed
- Screening issues similar to before CTD
  - Page referencing in QOS-CE

CTD Experience

- Module 1 different information than previous Part 1
  - e.g. GMP status, comparative data
- Chemistry portion similar to previous format
- Tricks for success
  - Set up clear templates before implementation
  - Build relationships with information providers