Industry Panel
CTD Experience

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CTD experience

- First CTD NDS filed in February 2003
- To date, filed 6 NDS, 7 SNDS, 47 NCs and 35 CTAs in CTD format for both Bio and Pharma submissions
- Most NDS and SNDS are based on EU and US, fair number built from scratch also
- Overall a very easy transition to CTD format
- When working from a EU/US based submission, find a high level of compatibility such that no module requires significant modification
- Mostly supplementing M3 with additional information

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CTD experience

- Time savings
  - no longer completing PCERT
  - using M2 summaries “as is” or with very minor modifications
- Time costs
  - Initially, more time to compile into an unfamiliar format and verify new x-referencing format
  - Currently, more time to create tabs
- CTD format does not specify single-sided printing, so transitioned to double sided printing for M4 and M5
  - cut courier and binder budgets to less than half

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CTD experience

- To date, no CTD formatting comments at Screening or during Review
- Hurdles for department included
  - adapting to different format for Clinical and Non-clinical summaries
  - relating the level of granularity to tabs
  - setting new conventions for x-referencing summaries and PMs
  - explaining to global sites why we still need to provide additional CM information for M3 and QOS-CE, even though Canada has adopted *ICH* CTD format

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