
Eli Lilly Canada Inc CTD Experience

CAPRA: June 1/2, 2004

**Bonnie A. Meloche
Regulatory Team Leader, Neuroscience & Oncology**

The Lilly logo is written in a red, cursive script font.

Answers That Matter.

LILLY CANADA

OUR CTD EXPERIENCE

- Filed all submission types in CTD format.
- Developed from 'scratch' or using US or European files.
- CTD NDS EXAMPLE:
 - Created using the EU file.
 - Module 1 created in-house.
 - Module 2 had the most extensive changes including:
 - Section 2.3 – Quality Overall Summary QOS-CE
 - Section 2.7.6 - Synopsis of individual studies
 - Cross-referencing all sections to Health Canada's specifications.
 - Module 3 changes included: addition of regional specific information such as executed batch records for CT lots

LILLY CANADA

OUR CTD EXPERIENCE (cont'd)

- CTD NDS EXAMPLE (cont'd):
 - Module 4 and 5 were used with minimal changes.
 - No screening comments received.
- Future submissions would include as much as possible electronically.
- Savings in preparation time not seen for initial CTD NDS.
- Anticipate faster CTD preparation for future filings.