

Health Products and Food Branch

Your Health and Safety - Our Priority

HC-Experience with eCTD Format Reviewer Readiness Survey

CAPRA Symposium

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Canada



The logo for E-Review, featuring a stylized '@' symbol followed by the word 'Review' in a bold, sans-serif font.



Health
Canada

Santé
Canada

Reviewer Readiness Survey

Q1. Have you ever reviewed a submission in electronic format?

- 35% of the person who completed the survey said yes.

Q2. How many submission in electronic format have you reviewed?

- 60% reviewed 1-2 submissions,
- 30% reviewed 3-10 submissions,
- 10% reviewed > 10 submissions.

Reviewer Readiness Survey

Q3. How recently have you reviewed a submission in electronic format?

- 85 % reviewed a submission in electronic format within the last year.

Q4. How many hours of a normal working day were you able to use the electronic format to perform your review?

- 15% for 2 hours or less,
- 65% for 3-4 hours,
- 20% for 5-7 hours.

Reviewer Readiness Survey

Q5. What percentage of the submission did you review electronically (versus reviewing the paper version)?

- 1/4 reviewed 25% electronically,
- 1/4 reviewed 50% electronically,
- 1/4 reviewed 75% electronically,
- 1/4 reviewed 100% electronically.

Reviewer Readiness Survey

Q6. What are the benefits of reviewing a submission in electronic format?

- Search capability / quick data retrieval.
- Hyperlink was convenient (when it worked) / faster access to referenced documents / needs dual computer screens.
- Ability to copy/paste tables/figures/texts from the submission to the review report.
- Easier to access data from different locations.
- The desk is less clutter.
- Fast/efficient.

Reviewer Readiness Survey

Q7. What were the disadvantages of reviewing a submission in electronic format?

- Paper documents still required in some case (e.g. group discussion).
- Can only view one page at the time/need to do side-by-side comparisons.
- Limited space on the computer screen.
- Ergonomic considerations for reading on computer screen for long periods/fatigue/eye strain/loss of concentration.
- No access to submission data when the network is not working.