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Electronic Review Symposium

December 3, 2019 – Toronto

CAPRA hosted a one-day symposium to provide an update on the Electronic Review activities from Health Canada.

Both Health Canada and Industry speakers presented their strategies, experiences and feedback on Regulatory Enrolment Process (REP), Structured Product Monographs, eCTD Pilot of Clinical Trials, and other projects.

Speaker	Topic
Joseph Mikhael Manager, Division of Systems Management (DSM), Resource Management and Operations Directorate (RMOD), Health Canada (HC)	Health Canada and eReview
Craig Anderson Business Analyst, Business Informatics Directorate (BID), RMOD, HC	Health Informatics Standards (Controlled Vocabularies, ISO and HL7 standards)
Joseph Mikhael Manager, DSM, RMOD, HC	Regulatory Enrolment Process (REP)
Craig Anderson Business Analyst, BID, RMOD, HC	XML/Structured Product Monograph (SPM) Update
Khaled Yahiaoui Sr. Publishing Specialist, RA, Merck Canada Inc. **Robin Shibish** Regulatory Operations Manager, AstraZeneca Canada Inc.	REP, SPM, eCTD CTAs and Pubic Release of Clinical Information (PRCI) A Canadian Industry Perspective on eReview Projects
Irena Pastorekova Regulatory Affairs Supervisor, DSM, RMOD, HC	eCTD Pilot for Clinical Trials, Changes to Clinical Trial Site Information (CTSI) form
Joseph Mikhael Manager, DSM, RMOD	**Canadian Clinical Drug Dataset (CCDD)**
Panel Discussion & Closing Remarks	