CHÉOS
Centre for Health Evaluation & Outcome Sciences

When is a Clinical Trial Application (CTA) Needed?

- Required for all Phase I, II and III studies that include drug, biologic and/or natural health product intervention.
- Phase IV studies – performed within the approved indication after the drug/biologic/natural health product has been approved by Health Canada for the market – are exempt from the CTA.

Examples of studies requiring a CTA:

- Investigational drug (no Drug Identification Number [DIN])
- Approved drug being studied outside of approved indication/clinical use (e.g. new disease state/new patient population, pediatric population)
- Approved drug being studies outside of approved dosing requirements (e.g. increased dose or change in dosing regimen)
- Approved drug being administered via unapproved route