



GVI Clinical Development Solutions (CDS) is an innovative CRO providing strategic consulting and hands-on clinical and regulatory support to biotechnology, pharmaceutical, diagnostic, medical device, and nutraceutical companies.

Our experience sets us apart, and allows us to deliver quality data in a shorter period of time and at a lower cost than other CROs.

CDS offers:

- A well rounded team with clinical development expertise across a multitude of therapeutic areas.
- Senior Clinical Research, Regulatory Affairs and Pharmacovigilance professionals with unique experience from careers in the pharmaceutical, biotechnology and CRO industries.
- Extensive contact networks with key therapeutic area leaders and high performing investigators.
- Customized services including: Clinical & Regulatory Strategy Development, Regulatory Submissions, Clinical Trial Monitoring, Project Management, Regulatory Affairs, Clinical Document Control, and Pharmacovigilance.
- Extensive networks and partnerships with ancillary vendors in areas not directly serviced by CDS, including Data Management, Central Labs, Large Scale Monitoring, etc.
- In-depth knowledge of efficient clinical trial processes enabling consistent delivery of quality data on time and within budget.

Our mission is to provide high quality services and solutions to maximize our clients' time and capital.

For further information on our services please contact:

The CDS Team
(204) 478-5607
(855) 499-3615

info@gvicds.com
www.gvicds.com

See summary of experience on reverse side.

DRUG CLASS	INDICATION	TRIAL PHASE	# PTS	# SITES	SERVICES*
Canadian ARO [†]					
Natriuretic Peptide	Acute Decompensated Heart Failure	III	300	12	Mon
P2Y12-Inhibitor	PCI	II	70	7	Mon
RNA Aptamer	Non-STEMI ACS	IIb	160	4	Mon
DPP-4 Inhibitor	CV Outcomes in Type 2 Diabetes	III	500	25	LCRA, Mon
Thrombin Agonist	Non-STEMI ACS	III	150	20	Mon
Cholesterol Lowering	High-Risk ACS	III	300	27	Mon
US ARO					
Chelating Agent	ACS	III	1,700	150	LCRA
US Biotech					
Cardioprotective Agent	PCI	IIa	120	5	PM, SS, SM
US CRO [‡]					
Kallikrein Inhibitor	CABG	II	300	38	Global PM
Kallikrein Inhibitor	CABG	II	344	35	Global PM
Heparin Reversal Agent	CABG	II	60	10	Sr. PM
US Generic Pharma					
Antiinflammatory/ Pain relief ointment	Grade I & II Hemorrhoids	II	70	3	Consulting
Canadian Specialty Pharma					
GP IIb/IIIa Inhibitor	PCI	III	1,700	100	Full service
Cardioprotective Agent	PCI	II	60	12	PM, SS, SM
Cardioprotective Agent	CABG	II/III	902	42	PM, SS, SM, Mon
Cardioprotective Agent	CABG	III	3,025	139	PM, SS, SM, Mon
Cardioprotective Agent	Cognitive Deficits in CABG	II	400	41	PM
Cardioprotective Agent	Hypertension & Type 2 Diabetes	II	160	12	PM, SS, SM, Mon
Cardioprotective Agent	Type 2 Diabetes	II	20	1	PM, SS, SM, Mon
Canadian Development Stage Biotech Companies					
Insulin Sensitizer	Type 2 Diabetes	II	40	3	PM
Insulin Sensitizer	Type 2 Diabetes	II	20	1	PM, Mon
Insulin Sensitizer	Type 2 Diabetes	II	64	12	PM, Mon
Medical Device	Cancer Biomarker Research	N/A	200	15	PM, SS
Cardiovascular, Diabetes, Diagnostics	Regulatory Affairs, Clinical, Drug Safety, and QA Support				

*Services abbreviations: PM - Project management; Mon - Monitoring; SS - Site selection; SM - Site management; LCRA - Lead CRA

[†]ARO - Academic Research Organization

[‡]CRO - Contract Research Organization