



**HART CLINICAL
CONSULTANTS**
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HCC Projects Therapeutic Expertise

Therapeutic Area	Study	Service Provided	IND/IDE/Phase
Cardiology			
MI intervention	Therapeutic hypothermia	<ul style="list-style-type: none"> - Case Proctoring - Study Monitoring 	IDE/Phase 2
Heart Failure (HF)	Right heart pressures in management of heart failure	<ul style="list-style-type: none"> - Case Proctoring - Study Monitoring 	IDE/Pivotal
	Ablation of the R Greater Splanchnic Nerve	<ul style="list-style-type: none"> - Study Monitoring 	IDE/Device Feasibility
	Treatment of ascites in CHF	<ul style="list-style-type: none"> - Site Management - Case Proctoring - Inventory management 	IDE/Pivotal
	Plasmid on myocardial tissue regeneration	<ul style="list-style-type: none"> - Case Proctoring - Study Monitoring - eTMF Management 	IDE/FIH Phase 1
	Injected plasmid to promote angiogenesis	<ul style="list-style-type: none"> - Case Proctoring - Study Monitoring 	IND/Phase 2
	Novel system for > +2 MR	<ul style="list-style-type: none"> - Project Management - Site Management - Case Proctoring - Study Monitoring 	IDE/Device Feasibility
	LV remodeling for dilated cardiomyopathy and decreased EF	<ul style="list-style-type: none"> - Site Management - Study Monitoring 	IDE/Pivotal
Hypertension / Renal Denervation	Infusion system with substrate	<ul style="list-style-type: none"> - Case Proctoring - Study Monitoring 	IDE/Pivotal

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Structural Heart	Scoring balloon of calcific aortic valve prior to TAVR	- Site Management - Study Monitoring	IDE/Early Feasibility
	Evaluation of closure device	- Case Proctoring	IDE/Pivotal
	Evaluation of safety and efficacy of Embolic Protection Device	- Case Proctoring	IDE/Pivotal
	Evaluation of safety and efficacy of stenting system of Ao arch repair	- Project Management - Site Management - Study Monitoring - Safety Management - Data Management	IDE/Pivotal
Vessel Intervention	Evaluation of lithotripsy technology for calcified coronary vessels	- Case Proctoring	IDE/Pivotal
	Contrast media conservation system in patients with renal impairment	- Case Proctoring	IDE/Pivotal
	DES therapy following PCI	- Case Proctoring - Study Monitoring	IDE/Pivotal
	Injectable sirolimus in setting in-stent restenosis	- Case Proctoring	IDE/Pivotal
AAA repair	AAA grafting system	- Study Monitoring	IDE/Pivotal
	AAA grafting systems	- Study Monitoring	IDE/Pivotal
Ischemic Stroke Intervention	Acute Ischemic stroke intervention	- Clinical Trial Management - Study Monitoring - Site / Study Management - Data Management - eTMF Management	IDE/Pivotal
	Evaluating safety & efficacy of thrombectomy procedures to treat acute ischemic stroke	- Full-service CRO <ul style="list-style-type: none"> ○ Project Management ○ Site Management ○ Study Monitoring ○ Data Management ○ Safety Management 	IDE/Pivotal

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Ischemic Stroke Intervention (cont.)	Acute ischemic stroke intervention	- Full-service CRO <ul style="list-style-type: none"> ○ Project Management ○ Site Management ○ Study Monitoring ○ Data Management ○ Safety Management ○ eTMF Management 	IDE/Pivotal Post-Market
	Acute ischemic stroke intervention	- Full-service CRO <ul style="list-style-type: none"> ○ Project Management ○ Site Management ○ Study Monitoring ○ Data Management ○ Safety Management ○ eTMF Management 	IDE/Pivotal
	Various technologies in neurovascular / stroke intervention	- Study Monitoring	IDE/Pivotal
	Aspiration system in setting of sub-arachnoid hemorrhage	- Case Proctoring	IDE/Pivotal
	Acute ischemic stroke intervention	- Study Monitoring	IDE/Pivotal
	Acute ischemic stroke intervention	- Case Proctoring	IDE/Pivotal
Peripheral Vascular			
Arterial Stenosis Intervention	Covered stent for treatment of carotid artery occlusion	- Full-service CRO / Global Study Management <ul style="list-style-type: none"> ○ Project Management ○ Site Management ○ Study Monitoring ○ Data Management ○ Safety Management ○ eTMF Management ○ IP Management ○ Site Payments 	IDE/Pivotal
	Stent with embolic protection device for treatment of carotid artery occlusion	- Case Proctoring	IDE/Pivotal

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Arterial Stenosis Intervention (cont.)	Imaging technology supporting intervention of occluded Iliac / SFA	<ul style="list-style-type: none"> - Case Proctoring - Study Monitoring 	IDE/Pivotal
	Safety and efficacy of DCB in SFA	<ul style="list-style-type: none"> - Project Management - Site Management - Case Proctoring - Enrollment Specialist - Study Monitoring - eTMF Management 	IDE/Pivotal
Clinical Quality BiMO Inspection			
N/A	Site BiMO prep	<ul style="list-style-type: none"> - Quality audit 	N/A
Diabetes			
Diabetes and Glucose monitoring systems evaluation	Updated continuous glucose monitor	<ul style="list-style-type: none"> - Site Management - Study Management - Study Monitoring 	510(k)
	Continuous glucose monitor	<ul style="list-style-type: none"> - Clinical Lab Management - Study Monitoring 	510(k)
	Impacts of Obstructive Sleep Apnea on HBA1C	<ul style="list-style-type: none"> - Study Monitoring 	Post-market device study
Diagnostics			
Detection systems/ wearables – biometrics, symptoms, biomarkers (sepsis, sleep, HF)	Lab sample testing for detection of sepsis	<ul style="list-style-type: none"> - Study Monitoring - Project Management - Medical Writing 	IDE/Pivotal IVD
	Study of various wearable devices for collecting various biometrics	<ul style="list-style-type: none"> - Study Monitoring 	IDE
	Wearable device for detection of heart failure symptoms	<ul style="list-style-type: none"> - Study Monitoring - eTMF Management 	IDE Consecutive Phases: 1. Lead In 2. Phase 1 3. Phase 2
	Cardiac assay biomarkers	<ul style="list-style-type: none"> - Study Monitoring 	Observational
GI Intervention			
Obesity	Gastric balloon System	<ul style="list-style-type: none"> - Case Proctoring 	IDE/Pivotal

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Men's Health / Prostate Intervention			
Urinary Obstruction Intervention	Ablation system for prostate resection	- Study Monitoring - Clinical Quality Audit	IDE/Pivotal
Oncology			
Tumor, Diagnostic (infusion)	Infusion of investigational product in solid tumor mass	- Case Proctoring	Phase I
Orthopedics & Robotics			
Osteoarthritis, Knee	Knee System	- Project Management	Post Approval
Respiratory			
Respiratory/Pulmonary Intervention, treatment	Chronic rhinitis	- Project Management - Site Management - Study Monitoring	IDE/Pivotal Post Approval
	Treatment to reduce mucus build up on bronchial tree	- Study Monitoring - BiMO Audit preparation	IDE
	CPAP devices for chronic obstructive sleep apnea	- Study Monitoring	IDE/Pivotal
	Drug-eluting scaffold for treatment of sinus cavity polyposis	- Study Monitoring	IDE/Pivotal
	Aspiration system in setting of acute pulmonary embolism	- Case Proctoring	IDE/Pivotal
	Clot retrieval in setting of acute ischemic stroke	- Full-service CRO / Global Study Management <ul style="list-style-type: none"> ○ Project Management ○ Site Management ○ Study Monitoring ○ Data Management ○ Safety Management 	IDE/Pivotal
Psychiatry			
AI Algorithm/Detection	Algorithm for facial detection of depression	- Study Monitoring - eTMF Management	AI/Feasibility

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Surgical Intervention			
Surgical Intervention, various	System for subjects undergoing resection of tumor in large intestine	<ul style="list-style-type: none"> - Full-service CRO / Global Study Management <ul style="list-style-type: none"> ○ Project Management ○ Site Management ○ Study Monitoring ○ Data Management ○ Safety Management ○ IP Management ○ eTMF Management 	IDE/Pivotal
	Surgical system instruments in women with early-stage breast cancer Robotic technology for various body systems	<ul style="list-style-type: none"> - Study Monitoring - eTMF Auditing 	IDE/Safety and Feasibility
Vessel Closure			
TAVR	Closure device for large bore arteriotomy (s/p TAVR procedures)	<ul style="list-style-type: none"> - Case Proctoring 	IDE/Pivotal