bioaccess®

The first-in-human CRO for the Americas.

First-in-human and early feasibility trials for medical devices. We plan around your FDA endgame from Miami, then run the study where it moves fastest across the Americas.

COMPANY OVERVIEW · 2026 · bioaccess® (IMH Assets Corp.), Miami, FL

THE PROBLEM

The runway trap: why many startups stall before human data.

01

The data is the fundraise.

Investors want human data before the next round. No proof-of-concept, no Series A.

02

The U.S. path burns runway.

Ethics, IDE, contracting and slow enrollment can consume 18–36 months before first-patient data.

03

Big CROs deprioritize you.

A 10-patient first-in-human study sits behind Phase III mega-trials on a large CRO's roster.

The trap isn't the science. It's the timeline.

WHO WE ARE

First-in-human specialists since 2010.

bioaccess® anchors on U.S. regulatory strategy (FDA Pre-Sub, IDE/IND) and executes across Latin America, with an affiliated Miami cardiovascular site for Phase 1 and early device studies.

2010
founded

50+
client companies

50+
FIH and early feasibility studies supported

30+
team members

100+
investigative sites in our network

19
Latin American & Caribbean countries

SELECTED CLIENTS SINCE 2010

AliveCor · Omron Healthcare · LG · SI-BONE · Cook Medical · Establishment Labs · Inspire Medical · PAVmed · enVVeno · ReGelTec · Axoft · Newrotex · Avantec Vascular (Nipro) · Sim&Cure · Corza Medical · Mitralign · ClarVista

Staff, site and study counts are experience-based estimates from programs since 2010; the 19-country footprint covers device registration and market access. Names shown as text; no endorsement implied.

WHAT WE DO

One partner from protocol to proof.

1 First-in-human trials

End-to-end FIH studies for novel devices: protocol, submissions, sites, monitoring, data and reporting.

2 Early feasibility studies

Small-cohort EFS for medical devices, including studies planned under an FDA IDE.

3 Regulatory strategy & FDA data bridge

FDA Pre-Sub / Q-Sub and IDE planning, so data from outside the U.S. plugs into your U.S. submission.

4 Site search & selection

Investigators and sites matched to your device from a network of 100+ sites across Latin America.

5 Logistics & sponsor support

Investigational-device importation, clinical-trial insurance arranged, consent forms in Spanish or Portuguese.

6 Device registration & market access

Post-study registration with ANVISA, INVIMA, COFEPRIS, ANMAT, ISP and DIGEMID, scoped as a separate file.

We also support first-in-human and early feasibility work for drugs, biologics and radiopharmaceuticals (Lu-177, Ac-225, Ga-68).

HOW A PROGRAM RUNS

Protocol to last patient, in one written timeline.

Weekly progress reports to you and your investors, plus milestone reports written for your data room and board deck.



Weeks 1–2

Map the fastest path

Regulatory route, country and site recommendations, indicative timeline and budget.

Weeks 2–8

Ethics & regulator filing

Dossier assembly; ethics committee and national regulator submissions.

Months 2–3

Activation & first patient

Contracts, investigator training, device import, first patient in.

Months 3–10

Enrollment & monitoring

ACRP-certified monitoring, EDC data capture, safety reporting under GCP.

~Month 12

Last patient, last visit

Final protocol visit and database lock.

Month 12+

Data package

Biostatistics, clinical study report and FDA-anchored regulatory dossier.

Representative planning estimates from programs run since 2010. Ethics and regulator review windows vary by study; we confirm timing per protocol.

THE FIH-12™ GUARANTEE

Your timeline, in writing. If we're late for reasons we control, you don't pay us to be late.

100%

of our project-management and monitoring fees credited until last-patient-last-visit if we miss the protocol-to-LPLV timeline for reasons within our control.

bioaccess® controls

Regulatory strategy and submissions, site selection and activation, device import logistics, monitoring, data management, biostatistics and the CSR.

You control

Investigational product supply, protocol decisions and design freeze, pass-through funding, document turnaround.

Sites control

Local enrollment pace, institutional contracting and staff scheduling.

Regulators control

Ethics and national regulator review timing, and import permits.

Exclusions (sponsor changes, regulator decisions, site performance, patient availability, safety events, force majeure) and full terms are defined in your proposal before work begins.

WHERE WE RUN TRIALS

Where we run first-in-human trials.

Lead first-in-human jurisdictions

Chosen for fast, predictable approval paths

El Salvador
SRS · CNEIS ethics

Panama
MINSA · Decree 21 (2026)

Dominican Republic
DIGEMAPS

Chile
Accredited CEC · ANDIM / ISP

Costa Rica
CONIS · accredited CEC

Active FIH & EFS programs

Run on request for clinical or commercial reasons

Colombia
INVIMA · local bioaccess® entity

Mexico
COFEPRIS

Brazil
ANVISA

Paraguay

United States
Affiliated Miami site · FDA / IRB

Support on request

Protocol-specific feasibility first

Guatemala
MSPAS / DRCPFA

Venezuela
MPPS / INHRR

Argentina · Peru · Uruguay

Bolivia · Honduras · Nicaragua

Belize · Canada

Device registration and market access cover 19 Latin American & Caribbean countries. Regional offices: Bogotá, Mexico City, Santiago, São Paulo, Buenos Aires.

EXPANDING COVERAGE

Guatemala and Venezuela, scoped per protocol.

Guatemala

MSPAS, THROUGH DRCPFA

— Ministerial Agreement 206-2021 (in force since October 2021) sets a dedicated dossier for medical-device investigations.

— Authorized ethics committee approval comes first; each committee runs its own calendar.

— Regulatory clock: up to 30 business days after a complete file, plus defined query periods. Not a startup promise.

— Protocol in Spanish; the investigator brochure may stay in its original language with a Spanish summary.

Venezuela

MPPS, TECHNICAL REVIEW BY INHRR

— INHRR reviews clinical-trial applications for drugs, biologics and medical devices; SACS handles sanitary control and device registration as a separate file.

— Spanish protocol package: investigator brochure, informed consent, insurance and ethics approval. We run the submission.

— Candidate sites in Caracas, Valencia, Maracaibo and Barquisimeto, confirmed per protocol.

— Studies designed with FDA submission in mind: EDC, structured adverse-event reporting, source data verification.

Both start with a protocol-specific feasibility assessment; we don't claim a study is already running there. Foreign data is FDA-eligible under 21 CFR 812.28 only when the rule's conditions are met.

REGULATORY FRAME

Data built for your U.S. submission.

Every study is planned around your FDA endgame. You receive an English-language, monitored data package, a clinical study report and an FDA-anchored regulatory dossier, plus a data-bridge strategy that shows exactly how the OUS data plugs into your U.S. submission.

Plain terms: foreign clinical data can be eligible for FDA acceptance under 21 CFR 812.28 when the rule's conditions are met. FDA decides on a submission-by-submission basis; eligibility is not clearance or approval.

ISO 14155	Good clinical practice for medical-device investigations
ICH E6 (GCP)	Good clinical practice for drug and biologic trials
21 CFR 812.28	FDA acceptance of foreign clinical data for devices
21 CFR 312.120	FDA acceptance of foreign clinical data for drugs and biologics
FDA pathways	Pre-Sub / Q-Sub, IDE, 510(k), De Novo, PMA, HDE

TRACK RECORD

Our clients' data has anchored real milestones.

Axoft	**Neurotechnology · Panama**	Panama first-in-human at The Panama Clinic (4 patients) → 11 patients implanted worldwide → $55M Series A (April 2026).
ReGelTec · HYDRAFIL®	**Spine · Colombia & Panama**	OUS data (75 patients) → CE Mark and an FDA IDE pivotal trial; peer-reviewed results in Pain Physician (Jan 2026).
enVVeno Medical · enVVe®	**Vascular · Colombia**	Latin American first-in-human foundation → FDA IDE approval; U.S. pivotal study authorized April 2026.
PAVmed · PortIO™	**Vascular access · Colombia**	First-in-human intraosseous infusion program; results published in the Journal of Vascular Access.
Avantec Vascular (Nipro)	**Venous · El Salvador, Mexico, Colombia**	FIH / early studies of the Sangria™ system: PI and site selection, ministry submissions, $10M trial insurance, device import.
Newrotex · SilkAxons™	**Peripheral nerve · Panama**	First-in-human implantation program at The Panama Clinic, begun August 2025.

Also supported early clinical studies for Mitralign (later acquired by Edwards Lifesciences) and ClarVista Medical (later acquired by Alcon). Devices shown are investigational unless stated; no FDA clearance or approval implied, and no causal link between our services and funding or acquisition outcomes is claimed.

LEADERSHIP

The team driving execution.



Julio G. Martinez-Clark

Co-Founder & CEO

Also CEO of Amavita Research Services LLC. Creator of the Global Trial Accelerators podcast (125+ episodes).



Pedro Martinez-Clark, MD

Co-Founder & Chief Medical Officer

Harvard-trained interventional cardiologist, ABIM Board Certified in Cardiovascular Disease, with 27+ years in interventional cardiology and clinical research.



William O'Neill, MD

Co-Founder & Medical Director

Led the team that performed the first transcatheter aortic valve replacement in North America (Beaumont Hospital, 2005). MSCAI.



Monica C. Mora

Chief Operating Officer

Leads operations, overseeing first-in-human trials across ten Latin American markets: site qualification, regulatory strategy, logistics, and compliance.



John Myklusch

Chief Financial Officer

Leads finance and strategic planning at bioaccess®. A CPA and Certified Exit Planning Advisor (CEPA), and Principal at AmbitionCFO.

Behind them: an ACRP-certified clinical research team, and an affiliated Miami site (Amavita Research) for Phase 1 and early device studies in the U.S.

bioaccess®

NEXT STEP

Send us your device, target country and timeline.

We'll come back with a concrete plan: regulatory route, country sequence, timeline and a study-specific budget.

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Helpful to include

- What the device is and does
- Development stage and preclinical evidence in hand
- Target population and indication
- Preferred country, if you have one
- Your U.S. pathway and investor milestone

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