



***International Full-Service
Contract Research Organization***

North America * Europe * Israel * Africa * Asia Pacific

Phase I-IV Studies

Device Studies

Registration Studies

Marketing Studies

Outcome Studies

Epidemiology Studies

Nutra- & Cosme-ceutical Studies

Risk Evaluation and Mitigation Strategy (REMS)

Project
Management

Monitoring

Patient
Recruitment &
Retention

Data
Management

Biostatistics

Regulatory
Affairs

Medical
Affairs

Device
Surgical Wet
Lab Set-Up

Certification
Management

Investigator/
Advisory Board/
KOL Meetings

24 Hour Travel
Agent Support

Pharma Studies

Device Studies

Registration
Studies

Marketing Studies

Outcome Studies

Epidemiology
Studies

Nutraceutical
Studies

Cosmeceutical
Studies

Risk
Evaluation &
Mitigation
Strategy
(REMS)

Independent
Consulting

Functional
Outsource



WE'VE WORKED WITH A DIVERSE
SPONSOR BASE.



HOW CAN WE HELP YOU?

JANIX Mission Statement:

We're not "just" the CRO, we're your Team,
remaining dedicated to your success.

ABOUT US: Founded in 2004, **JANIX** is an efficient, metric based clinical research organization (CRO) with a global footprint of operations including North America, Europe, Israel, Africa and Asia Pacific.

Our mandate recognizes the need within the medical research community for quality clinical services backed by experience, ICH/GCP training, protocol adherence, and leadership while offering significant cost advantages.

Representing a vertically integrated and full service Clinical Research Organization (CRO), **JANIX** provides a collaborative and personalized approach to meet sponsor study requirements in a manner that sets us apart from most clinical research service providers.

The key tenets of our business ethos include clear and open lines of communication, sound expectation management, implementation of objective performance metrics, and project accountability at all levels.

Our clients have ranged from big pharma to the emerging growth biopharma, and specialty sector, conducting Phase I-IV clinical studies, and device, registration, marketing, outcomes, cosmetic and nutrition trials.

We've worked with a diverse Sponsor base. How can we help you?

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Email: BD@JANIX.com

JANIX: clinical research solutions that work

Your Prescription for Clinical Research Success (SM)

PROJECT MANAGEMENT SOLUTIONS: The key tenets of our management style: clear and open lines of communication, defining the project measure of success, sound expectation management, implementation of objective performance metrics, and accountability. Our project playbook, gantt charts, reports and metrics give our Sponsors confidence that the work is being done and which allows JANIX to demonstrate our project management ethos.

MONITORING SOLUTIONS: JANIX CRAs are not “just” monitors, they function as site managers, meaning, our CRAs are responsible for developing an engaging communication plan with their site and assist JANIX managers with site activation by being responsible for ethics and regulatory document review and completion, by-site metric reporting, and participating in ongoing patient recruitment & retention activities, in addition to monitoring.

INTERNATIONAL & EMERGING MARKET SOLUTIONS: In addition to serving western countries (e.g., North America & EU), we also serve Africa, Middle East, and Asia Pacific and we price our services based on local costing. Example: in South Africa our costs are about 30% less than US services. Our regulatory affairs staff’s local know-how will successfully guide your international projects.



DATA MANAGEMENT SOLUTIONS: We own an EDC system. Other CROs license expensive software (e.g., Oracle® Clinical) then pass the additional costs onto their client. We don’t do that, at JANIX our *low overhead equals low cost data management for our clients.*

BIOSTATISTICS SOLUTIONS: CDISC standards including models; SDTM, ADaM, ODM, & Define.xml. Ability to develop: sample sizing; study design; protocol writing; randomization; statistical analysis plan; SAS programming; table production for study reports & other vital regulatory submissions; encompassing statistical analysis, reporting, corroboration, & review overall services to achieve numerical validity.

ENROLLMENT SOLUTIONS: Through patient recruitment and retention strategies JANIX provides the knowledge, implementation, and back-end support for sponsors to reach patient enrollment goals in a cost-effective and timely manner. Examples : activity calendar; brochures/posters; pocket protocol; chart ID & alert notice; pre-screening worksheet; study visit/roles cards; outreach services; physician mailing; speaking engagements; SC telecons; transportation program; comprehensive market research; study awareness building strategies; mixed media advertising campaigns; call center services; community outreach; general site support services; performance metrics analysis.



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MEETINGS SOLUTIONS: Let us plan your next meeting! We've successfully executed: investigator meetings; advisory board / KOI meetings; data safety board constitution; device/surgical training; corporate meetings / retreats; off-site dinners & entertainment. We've performed the following: generate presentations & data safety board charter; find key opinion leaders (KOL); online registration; facility inspections/ hotel mgmt.; logo design and graphics; air travel & 24/7 travel assistance.

DEVICE WET LAB SOLUTIONS: We have the experience and the SOPs to ensure proper training of physicians who will ultimately be the users of product. We have the know-how in resourcing the biologic (e.g., animal parts), or synthetic materials needed for the training session. Let us set up the wet-lab, and dispose of the hazardous materials. We've organized wet-labs in US and international settings and understand the local requirements with accessing biologic and disposal of materials per local law. The tenets of our training: handling of procedural for dissection, haemostasis and anastomosis; Understanding the properties, capabilities and limitations of these devices; developing the theatre team to perform and train physicians; certifying training per sponsor requirements.

flexible solutions for clinical trial needs

MEDICAL AFFAIRS SOLUTIONS: Our medical monitors will ensure patient safety and study integrity while providing effective communication with the Sponsor. Depending on the scope, JANIX medical monitor can participate in the formative stages of the study for structured adverse event determination, monitoring, and reporting systems, including standardized forms and protocols for referring and/or treating subjects experiencing adverse events.

CERTIFICATIONS SOLUTIONS: We will work with your reading lab vendor to ensure a streamlined approach to required study certifications. We will develop and then gantt a plan of action, and implement technician teleconferences, including a peer support network to achieve rapid turnaround and completion times. Quick site certifications mean quick site activation with no enrollment delays.

A highly customized and personal approach set us apart from other service providers and translates to increased customer success and long term partnerships with our clients. We've worked with a diverse Sponsor base. How can we help you?



JANIX: clinical research solutions that work

Your Prescription for Clinical Research Success (SM)

PHARMACEUTICAL TRIAL SOLUTIONS:

JANIX has the capacity to cover a broad range of activities paramount to successful pharmaceutical research, from small early development Phase I trials to large global Phase III trials. Beginning with feasibility and extending to study design, protocol, and case report form development, JANIX offers a flexible service menu. A selection of tailored services can be contracted to minimize costs and meet specialized client requirements.

REGISTRATION STUDY SOLUTIONS:

JANIX can work with local governments to ensure obligatory requirements for the import and sale of product can be met. JANIX will generate the submission of the registration application and the dossier to the local government, and where required, perform validation studies, per local law.

EPIDEMIOLOGY STUDY SOLUTIONS: The founder of JANIX is a trained epidemiologist, and master level biostatistician, thus conducting epidemiology studies and understanding the application of statistical design to the trial is a passion at JANIX. Let JANIX design and conduct your next cohort or case-control study!

DEVICE TRIAL SOLUTIONS: Let JANIX navigate your Class I, II or III product and provide clinical support, including wet lab training by our medical staff, if applicable. Seeking a CLIA waiver certificate? Let us handle your CLIA waiver study beginning with feasibility and extending to study design, protocol, and case report form development, JANIX offers a flexible service menu. A selection of tailored services can be contracted to minimize costs and meet specialized client requirements.



POST MARKETING STUDY SOLUTIONS:

Successful post marketing trial results helps turn science into sales. JANIX understands the unique challenges of conducting post marketing studies, from designing a protocol that tests a hypothesis while ensuring standard of care, to working with limited marketing department budgets. JANIX can help from trial design to publication, within budget realities.

OUTCOME STUDY SOLUTIONS: JANIX can execute outcomes research to help understand the end results of particular health care practices and intervention. End results include effects that people experience and care about, such as change in the ability to function. In particular, for individuals with chronic conditions—where cure is not always possible—end results include quality of life as well as mortality.



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NUTRACEUTICAL STUDY SOLUTIONS:

JANIX has formed an exclusive team to conduct studies on nutraceuticals. There is an emerging trend in the industry (also known as the "Fast Moving Healthcare Goods") to rapidly develop products (supplements, food products) that will meet the nutritional needs of individuals, especially the unique dietary needs of the elderly, which are the driving force behind the development of nutraceuticals and need for CRO collaboration. Let the JANIX team of experienced dietitians and medical staff develop and manage your next nutraceutical trial.

***“WE TRACK IT!
WE CHART IT!
WE GRAPH IT!”***

MEETING SOLUTIONS: Let us plan your next meeting! We've successfully executed: investigator meetings; advisory board / KOI meetings; data safety board constitution; device/surgical training set up; corporate meetings / retreats; off-site dinners & entertainment. We've performed the following: generate presentations; generate data safety board charter; find key opinion leaders (KOI); online registration; facility inspections/ hotel mgmt.; logo design and graphics; Air Travel & 24 /7 travel assistance.

INDEPENDENT CONSULTANT & FUNCTIONAL OUTSOURCING SOLUTIONS: The versatility of JANIX' service menu allows sponsor to combine any number of our service domains with those of other CROs, independent contractors and in-house staff for the assemble of a multi functional team ideally suited to conduct a trial, and to do so within budgetary realities. JANIX can function as a Full Service CRO, or we can offer consulting or functional outsourcing solutions.

COSMECEUTICAL TRIAL SOLUTIONS: The cosmeceutical market is growing rapidly, driven by consumer interest and the launch of innovative ingredients and finished products. Cosmeceuticals are divided into categories based on their active ingredients. The new trend in cosmeceuticals is combination products. These products might contain ingredients such as multiple antioxidants, retinol plus anti-oxidants, growth factors plus vitamin C, and other unique combinations. Although the individual ingredients in combination products have been studied, the combination of their active ingredients has not. More rigorous scientific studies are needed to ensure that biologic activity is maintained when ingredients are formulated together. JANIX offers a flexible service menu. A selection of tailored services can be contracted to minimize costs and meet specialized client requirements.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) SOLUTIONS: JANIX will design a strategy to manage a known or potential serious risk associated with a drug or biological product. REMS will be required if FDA finds that REMS is necessary to ensure that the benefits of the drug or biologic outweigh the risks of the product, and FDA notifies the Sponsor.



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Cosmeceutical Studies

Risk Evaluation & Mitigation Strategy (REMS)

Independent Consulting

Functional Outsource

- ▶ African Device Registration Study for Antibody Testing;
- ▶ A Phase III, Global, 100 Site, 750 Patient Study Investigating An Intraocular Treatment For Diabetic Macular Edema & a 650 Patient, Phase III Retinal Vein Occlusion;
- ▶ A Phase III, Global, Comparative Study to Evaluate the Efficacy and Safety of 5 Days of an Investigative Oral Suspension Versus a Comparator in Children with Acute Otitis Media;
- ▶ A Phase I, "Proof Of Concept" Study In MHC Non-Restricted Cytotoxic T-Cell Line In CML Patients;
- ▶ EU Device Registration for PCR Diagnostic;
- ▶ A Phase II, 42 Patient, 13 Site, Clinical Trial Investigating a Peptide in Patients with Asymptomatic CA125 Progression of Ovarian Cancer;
- ▶ A Marketing Study, 40 Site, 350 Patient, Observational Study on Risk Factors and Immune Responses in Severe Dry Eye Patients;
- ▶ A Phase III, Global, 50 Site, 189 Patient Study Investigating An Intraocular Treatment For Non-Infectious Intermediate Or Posterior Uveitis;
- ▶ Thailand Cardiac Device Registration Study;
- ▶ A Phase II, 9 Site, 45 patients, Renal Failure Study;
- ▶ Investigating a siRNA treatment Following Cardiac By-Pass;
- ▶ Global Epidemiology Study Cataloging Bacteria found in Eye Infections;



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HOW CAN WE HELP YOU?

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