



### **CLINICAL RESEARCH SOLUTIONS**

*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.*

### **About Us:**

JANIX is an efficient, metric based, full service clinical research organization with a global footprint of operations. Our mandate recognizes the need within the biopharma and medical device research & development industries for quality clinical services backed by experience, ICH/GCP training, protocol adherence, and leadership while providing significant cost advantages.

The flexibility of JANIX's service menu allows sponsors to combine our value added efforts with those of other contract organizations, independent contractors and in-house staff for the assembly of a functional team best suited for a particular clinical study.

[www.JANIX.com](http://www.JANIX.com)

### **SELECTED JANIX PROJECTS**

- ▶ A Phase I, "Proof Of Concept" Study In MHC Non-Restricted Cytotoxic T-Cell Line In CML Patients;
- ▶ African Device Registration Study for Antibody Testing;
- ▶ 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 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 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;
- ▶ A Phase II, 9 Site, 45 patients, Renal Failure Study Investigating a siRNA treatment Following Cardiac By-Pass;

### **Contact Us:**

**JANIX Corporate**  
 3850 W. Ann Rd. STE 110  
 North Las Vegas, NV 89031  
 Phone; +1-949-251-9800  
 Email: [BD@JANIX.com](mailto:BD@JANIX.com)

[www.JANIX.com](http://www.JANIX.com)

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**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**

**Nutraceutical Studies**

**Cosmeceutical Studies**

**Risk Evaluation and**

**Mitigation Strategy (REMS)**

# JANIX: clinical research solutions that work

Your Prescription for Clinical Research Success (SM)

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.

## FULL SERVICE MENU

- ▶ Project Management;
- ▶ Monitoring;
- ▶ Patient Recruitment & Retention;
- ▶ Data Management;
- ▶ Biometrics;
- ▶ Regulatory Affairs;
- ▶ Medical Affairs;
- ▶ Device Surgical Wet Lab Set-Up & Training;
- ▶ Investigator Meetings;
- ▶ Advisory Board / KOL Meetings;
- ▶ 24 Hour Travel Agent Support;

As a full service global CRO we support a wide range of activities unique to clinical research including management & monitoring, data management and biostatistics, medical and regulatory affairs, patient and clinical site recruitment and a host of other important services for phase I-IV studies, and device, registration, marketing, outcomes, cosmetic and nutrition trials.

*flexible solutions for  
clinical trial needs*

**RISK EVALUATION & MITIGATION STRATEGY (REMS):** 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 a REMS is necessary to ensure that the benefits of the drug or biological product outweigh the risks of the product, and FDA notifies the sponsor.

**METRICS SOLUTIONS:** JANIX is a metric based service provider. *“We Track It! We Chart It! We Graph It!”*

**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.

**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.

**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.



WE'VE WORKED WITH A DIVERSE SPONSOR BASE. HOW CAN WE HELP YOU?  
JANIX, Full Service Global Contract Research Organization. Your Prescription for Clinical Research Success (SM)  
www.JANIX.com or, email us: BD@JANIX.com