

# INVESTIGATOR SUPPORT SERVICES HAS SERVED THE BIOPHARMACEUTICAL INDUSTRY FOR OVER 20 YEARS.

We streamline and simplify research site selection in North America, deliver trial management services throughout India, and provide global medical communication services. Our exceptional depth of experience, geographic reach and emphasis on technology allow us to quickly and effectively respond to our clients' needs.



**Site Network - North America:** Our stringent evaluation process, blended with our expertise in site identification and long-term site relationships, consistently delivers best-in-class research sites matched to your study needs. Our sites are distinguished by their superior business practices, professionalism, motivation and reputation. We continually measure site performance against industry standards and eliminate poor performers, allowing you to focus solely on qualified sites.



**Trial Management - India:** As a provider of comprehensive clinical trial services, we have extensive experience managing large and logistically complex studies. Our service offerings cover the entire spectrum from regulatory approval to study closeout. We offer the largest site network in India, with over 1,100 research centers. Our proven site support model includes placing highly qualified, full-time coordinators at each site to orchestrate all day-to-day study activities. The hands-on approach of our operations staff, present in more than 25 cities across India, and our full-scale training and education programs, make us a leading provider of trial management services.



**Global Healthcare Contact Center:** Our full-service contact center provides communications services in over 20 languages to support your product development, promotion and safety programs with live agents, interactive voice response, web solutions, social media and a range of other solutions tailored to your program needs. With 400 call center seats, our trained lay and licensed healthcare professional agents accurately distribute and collect health-related information 24/7/365. We support your clinical trials and post-approval programs with our knowledge of and sensitivity to a wide range of medical communication needs while complying with applicable regulations.



## CONTACT US

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# SITE NETWORK – NORTH AMERICA

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ISS blends aggregate site intelligence with careful protocol review and needs assessment to offer clients an expanded choice of best-in-class research sites. We match optimal sites to your trial from our fully vetted network of over 1,600 investigators at 400 facilities across the United States, Canada and Mexico.

## SITE SCREENING

Sites must earn their place in the ISS network. Our stringent evaluation process ensures we only recommend highly skilled and experienced sites. Upon application, sites are scored on an extensive list of weighted criteria, including, but not limited to:



**Background Checks:** We carefully examine and verify business, physician and key staff credentials. We review curriculum vitae, medical licensure, board certification, news articles, public and court records, medical board discipline and FDA audits for fraudulent or negligent actions. Problematic investigators are barred from our network.



**Infrastructure:** We assess facilities and equipment through site visits and detailed capabilities surveys. Phase I units range from 5 to 50 beds, house 24-hour labs and pharmacies, and manage trials in special populations and healthy normals. Phase II-IV sites conduct inpatient and outpatient trials in a range of facilities: hospitals, academic centers, private practices and stand-alone research centers.



**Staff:** We qualify site staffing based on coordinator-to-active-trial ratio, tenure, ICH/GCP training, accessibility and responsiveness. Our board certified investigators average 15 years of research experience. We favor coordinators who are medically licensed and/or ACRP certified.



**Patients:** We evaluate patient access by practice database size, use of electronic medical records, referral sources and hospital affiliations. Enrollment and retention are evaluated on historical performance, use of advertising and community outreach, enrollment versus goal and retention rates.

## ONGOING SITE EVALUATION

Sites must continue to meet our performance benchmarks to remain in our network. Our metrics and investigator/staff tracking systems, combined with rigorous site re-evaluation, mitigate your site selection risk. We implement corrective action plans and provide resources for site improvement when necessary. Underperforming sites are eliminated from our network.

## PROTOCOL MATCHING

We promote your trial and elicit investigator interest from our extensive, private network of pre-qualified sites. If necessary, we can utilize our database of 300,000 physicians or our call center to reach larger groups throughout the world.

We provide sites meeting your specific requirements within 5 business days. Select as few or as many as you need. Connect directly with the sites for selection, study activities and payment.

The success of our processes and performance is evidenced by our high site selection rate, repeat business and site enrollment histories, all of which surpass the industry average. We have helped sponsors and CROs find the right sites for over 1,800 clinical trials.

## TRIAL MANAGEMENT – INDIA

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We provide turn-key solutions and logistical support for expert navigation of India's clinical trial environment. With the largest network of investigators and operations personnel, we actively manage sites and support study conduct throughout India.

Trial sponsors can accurately assess the practicality and cost of conducting trials in India with our comprehensive, protocol-specific feasibility analysis. Combining in-depth epidemiological data, national and regional incidence data and standard of care information with our expertise in subject recruitment, we provide an accurate projection of the impact India will have on your enrollment rates.

Each research site must pass a 150-point qualification visit that includes facility tours and research staff interviews. Study teams consist of 100% English-speaking personnel, fully trained in all prevailing regulations for research conduct. Our full-time study coordinators are deployed to a single site and dedicated only to your study, resulting in on-time enrollment, and high retention rates, data quality and integrity.

### OUR PERFORMANCE AND QUALITY METRICS SPEAK FOR THEMSELVES:



**Start-up:** US IND registered studies typically receive regulatory approval in India within 12 weeks. To date, we have a 100% acceptance rate with submissions to the DCGI.



**Enrollment:** We have enrolled over 2,000 patients on time or ahead of schedule. Randomization of the first patient, on average, occurs within 14 days of the site initiation visit and 98% of enrolled patients complete the trials.



**Compliance:** Of nearly 30,000 patient visits to date, less than 0.5% were missed.



**Data:** In recent global trials, our sites had 80% fewer queries than other participating sites. Our record of complete data acceptance has contributed to several USFDA NDA approvals.

### WE PROVIDE COMPREHENSIVE TRIAL MANAGEMENT OR A LA CARTE SERVICES, INCLUDING:

#### Pre-Trial:

- › Site identification and evaluation
- › Investigator selection and training
- › Coordinator placement
- › Study feasibility assessment
- › Document translation
- › Courier and support service vendor identification
- › Rapid regulatory submission and approval
- › Clinical Trial Material (CTM) import/export license procurement
- › IRB submissions
- › Protocol-compliant site preparation
- › Document collection and management
- › Source document template creation
- › Site initiation visit preparation
- › Patient pre-screening

#### During Trial:

- › Informed consent, screening and enrollment
- › Patient retention and compliance support
- › CTM distribution and logistics management
- › Central lab and sample coordination
- › Monitoring and audit visit coordination
- › Subject reimbursement
- › Trial master file maintenance
- › Serious adverse event reporting
- › Data management and performance tracking

#### Post-Trial:

- › Closeout visit coordination
- › Query resolution and document archival
- › CTM reconciliation and return
- › Final report to ethics committee
- › Payout settlement

# GLOBAL HEALTHCARE CONTACT CENTER


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As a single-source provider of contact center solutions for clinical trial recruitment and retention, adverse event reporting, consumer affairs, pharmacovigilance and product recall support, we help you successfully manage consumer and healthcare professional communications. We are experts at designing, implementing and managing tailored programs throughout the life of your product. Our logistics management, process control, training and quality assurance systems are unparalleled.


## CORE CAPABILITIES


- › **Operators:** Highly skilled and experienced communicators, our MDs, PhDs, nurses, dietitians and lay agents offer services in 20 languages.
- › **Technology:** Our HIPAA compliant and Safe Harbor certified contact center uses the highest-rated telephony and IVR equipment in the industry. We employ a fully redundant system, with every transaction protected by SSL encryption. Our extensive SOPs and rigorous testing and validation for each program ensure data quality and integrity.
- › **Process and Quality:** Our comprehensive quality assurance program ensures proper call handling and full compliance with client standards. Staff recruitment and monitoring programs include in-depth new hire and project training, frequent call monitoring and calibration sessions.
- › **Web:** We develop and host targeted websites that engage all stakeholders and provide a single portal for patients and health professionals. With user-friendly interfaces and dynamic scripts, we share key product information, capture self-reported data and provide insights into website traffic and utilization.
- › **Metrics:** Data from all response channels is integrated into a single database, analyzed and reported with real-time access. Our robust reporting suite allows for a better understanding of inquiry trends and guidance to optimize your program.
- › **Social Media:** “Tune in” to web conversations about your business, markets or products. Our services include social media moderation and monitoring, web chat, blogging and email management.


## AREAS OF EXPERTISE

 **Patient Recruitment:** Our seasoned project managers translate complex protocols into effectual scripts to accurately guide callers and web respondents through study-specific screening. By reducing screen failures at the point of inquiry, we allow sites to concentrate on more qualified referrals.

 **Subject Retention and Compliance:** We identify and remove patients’ barriers to protocol adherence. Enrolled subjects remain engaged through coordinated, ongoing interaction, including personal and automated contact, diary capture, stipend management, SMS texting, mail fulfillment, appointment reminders and pre-visit instructions.

 **Pharmacovigilance:** Our pre- and post-marketing solutions complement your existing drug safety operations and mirror your corporate policies. Callers communicate with medical professionals experienced in adverse event and product quality complaint intake, processing and documentation.

 **Consumer and Medical Affairs:** Our brand representatives are trained to handle complex customer interactions. We provide accurate information to assist with educating patients and healthcare professionals on safe and effective medication use.

 **Risk Evaluation and Mitigation Services (REMS):** We administer universal education programs to healthcare professionals and patients on the safe and appropriate use of products via direct mail, telephone, web and field teams. Programs are intelligently designed to address product-specific risks and to ensure full compliance with FDA directives and prescriber lists.