



The company of specialists.

www.i3global.com

Pharmacovigilance Services: Asia-Pacific Region

Comprehensive, high-quality case processing and call center capabilities

i3 employs a team of experienced health care professionals located in Pune, India, to deliver outsourcing capabilities of the high quality you've come to expect from i3, but at a lower overall cost.

We adhere to global standard operating procedures (SOPs) and train all of our pharmacovigilance teams in the same core curriculum to deliver consistent quality and compliance everywhere we operate around the world.

Our current India-based offerings include:

- **Case processing services** for investigational and marketed products, including medical review
- **Call center services** for marketed products

An experienced pharmacovigilance team

The i3 pharmacovigilance team in India has a proven track record for providing high-quality deliverables, such as MedWatch and CIOMS reports, while adhering to all regulatory guidelines and timeframes.

Team members include physicians and pharmacists with both clinical and pharmacovigilance experience, and pharmacovigilance coordinators with substantial safety experience. We also require our on-site medical reviewers to be registered as physicians in India.

Expert adverse event case processing

Some key reasons for outsourcing your case processing to our team in India include:

- Low-cost, high-quality services
- Experienced pharmacovigilance staff
- A complete team of health care professionals
- Adherence to quality and regulatory standards—as evidenced by a 99.9% on-time regulatory reporting rate

Outsourcing in India with i3: Part of a smart global strategy

To help sponsors capitalize on the cost advantages of outsourcing a wide array of pharmaceutical services without sacrificing quality, i3 has established a significant presence throughout India that includes:

- An experienced base of operations with headquarters in Gurgaon and major offices in Mumbai and Pune
- Large-scale clinical development operations that offer:
 - An extensive network of local investigators and 500+ sites
 - Dedicated clinical monitoring and project management teams
 - Experience from 24 global studies at more than 200 sites
- A full complement of data management experts
- A comprehensive, state-of-the-art IT infrastructure featuring:
 - High-speed telecommunications capabilities
 - Leading technology support services, including provisioning and desk-side/end-user support
- An experienced and continually expanding pharmacovigilance team
- Complete functional service provision (FSP) capabilities
- Well-equipped, safe, modern, and comfortable working environments



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As a fully-staffed case processing unit, the i3 team in India is able to process adverse event reports up to and including submission using the Adverse Reaction Information System global (ARISg™) safety database or the sponsor's safety database.

From managing all of your adverse event case processing operations including call intake, to developing individual case safety reports, our India-based case processing services are:

- Fully customizable
- Compliant with 21 CFR Part 11
- Consistent with i3's exacting quality standards worldwide

Part of a state-of-the-art multilingual call center network

i3 has years of experience providing highly responsive global call center services that include:

- Receiving adverse event reports
- Receiving product quality complaint reports
- Fulfilling medical inquiries

Our call center in India is staffed with experienced health care professionals who are trained to handle all three of these key areas of inquiry, enabling us to meet your callers' needs with one telephone call hosted by a single representative.

The Pune-based operation is part of i3's global call center network, which employs a highly scalable, flexible, and adaptable system that allows agents to be added across a wide geography and can quickly route calls to agents fluent in the language of the caller based on originating region. Agents network-wide have the ability to cover approximately 150 languages via real-time language translation technology.

In addition, we have established local access numbers in more than 170 countries around the world, and can assist you in porting your existing call center numbers over to our system to present your callers with a seamless interface.

Extraordinary resources, all dedicated to your success

Our relationship with InVentiv Health puts us on a strong footing financially, with resources that keep us exceptionally strong—starting with every i3 expert who partners with you in a way that builds real trust between your team and ours.

As you think about your organization's outsourcing needs, consider what i3's commitment to your success means:

- Our corporate values, culture, and business strategies are consistent with yours
- We share your passion for science, quality, and the patient
- Therapeutic expertise in your areas of interest
- Scientific breadth throughout all businesses
- Flexible project and partnership models that align with your business needs throughout the world

Find out how i3's specialized approach and proven local resources in India can give your team the help with case processing and call center operations it needs to focus on more strategic safety activities.

Contact us

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www.i3global.com

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