

## Your Task Isn't Easy

Nonclinical development of drugs isn't easy, especially if you're going it alone. Safety program design and management, laboratory qualification, due diligence activities, issue analysis and resolution, and regulatory submission preparation all require unique expertise and experience to meet the high quality standards your company and regulatory authorities expect. It's hard to find that breadth of expertise and experience in any one individual.

## Data Management Dilemma

Managing nonclinical data can be challenging. Preparing reports from disparate systems is time consuming and costly. You need compliant and user-friendly applications that aggregate data, facilitate decision-making, shorten timelines, and reduce costs. You also want visualization and analysis tools that allow you to make the most of your study data.

## Do More With Less (and do it faster!)

Pharma is undergoing a metamorphosis. No matter your size, you are being asked to produce more with the same or fewer internal resources. You're being asked to do it faster and with more agility. To deliver, you're going to need outside resources that produce the high quality support and products you need - on time and within budget.

## WE CAN HELP YOU ACHIEVE YOUR GOALS

**For a Confidential Assessment of  
How INDS Can Assist You,  
Contact Us Today:**

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**Integrated Nonclinical  
Development Solutions**

He had to work alone...

...but you don't

Let **INDS** Help

Agile ◀

Experienced ◀

Focused on Your Needs ◀



# OUR TOXICOLOGY EXPERTISE

## Nonclinical Safety Program Design

- ▶ Idea to registration
- ▶ Traditional and innovative paradigms
- ▶ Mechanistic and investigative studies

## Safety Program Management

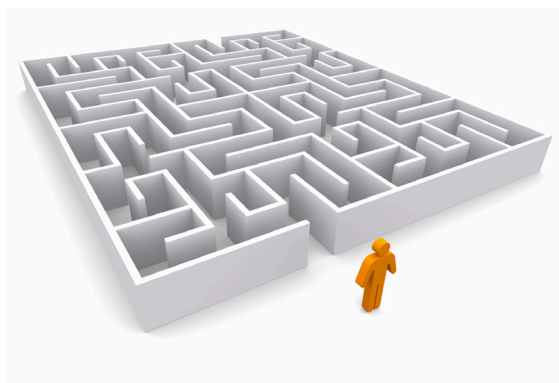
- ▶ Laboratory qualification
- ▶ Study placement and monitoring
- ▶ Expert data and report review
- ▶ Issue analysis and resolution

## Regulatory Submission Preparation

- ▶ Pre-IND, IND, IMPD, NDA, MAA, IB
- ▶ Representation at regulatory agencies

## Due Diligence

- ▶ Conduct of and preparation for licensing and regulatory inspections



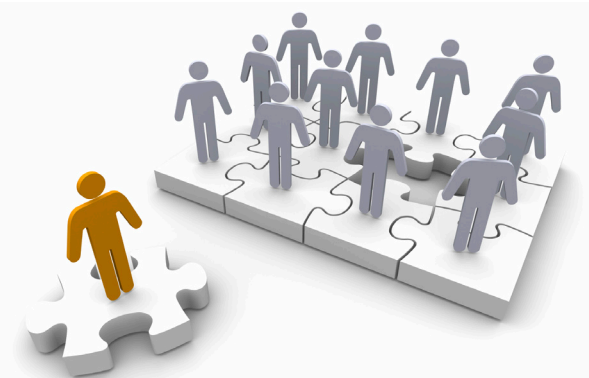
INDS utilizes a team approach to deliver solutions to our clients. Our team consists of board certified toxicologists, veterinarians, and information technology and business operations experts with more than 100 years of combined experience in the pharmaceutical industry.

### We have a proven track record of:

Advancing over 120 compounds in all major therapeutic areas to clinical trials, using both traditional and alternative paradigms, including filing the industry's first exploratory IND.

Advancing compounds to market, including several first-in-class drugs (Cognex®, ReZulin®, Neurontin®, LYRICA®) and the world's best selling drug Lipitor®, through design and execution of standard studies and extensive mechanistic investigations.

Developing innovative informatics solutions including state-of-the-art data warehousing, data visualization, interpretations tools, and automated report generation.



# OUR TECHNOLOGY EXPERTISE

## Data Warehousing

- ▶ Data mining within and across studies
- ▶ Graphical data representations
- ▶ Historical control reference ranges

## Automated Reporting

- ▶ Statistical summary tables and data listings
- ▶ Study interpretations interface
- ▶ Pre-populated protocols and study reports
- ▶ CTD tabular summaries

## Study Management

- ▶ Study inventory interface
- ▶ Study milestones, study design, financials

## Portal Development

- ▶ Single entry point to integrated applications

## Integrated Nonclinical Development Solutions Put Our Experts To Work For You

### THE INDS ADVANTAGE

The specialized, complementary expertise of our team members enables INDS to provide your nonclinical safety support from target selection to product registration. Our data management and information technology specialists work closely with our toxicologists to deliver software solutions that truly reflect end user needs for ease-of-use and flexibility.

### YOUR NEW PARTNER

When you engage INDS, you gain a partner, not just a service provider. Your problems and challenges become our problems and challenges. We work to provide solutions as if our company depends on the outcome, because it does. We strive to develop lasting relationships and are committed to your long-term success.

## Let INDS Help You With The Heavy Lifting

### COMMITTED TO YOUR SUCCESS

Whether you lack internal nonclinical safety expertise or need to supplement your internal resources to meet peak demands, contact INDS. We have the know-how you need to succeed.

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