





# *Focused Resources Driven to Service Your Needs*

Drug development is a complex process with many components that need to be coordinated to demonstrate safety and efficacy, and to maximize your drug's likelihood of gaining approval and succeeding in the marketplace.

At Covance, we know the significant competitive pressures you face to develop and launch drugs backed by strong data. We understand the demands placed on you and have built our business around your needs.

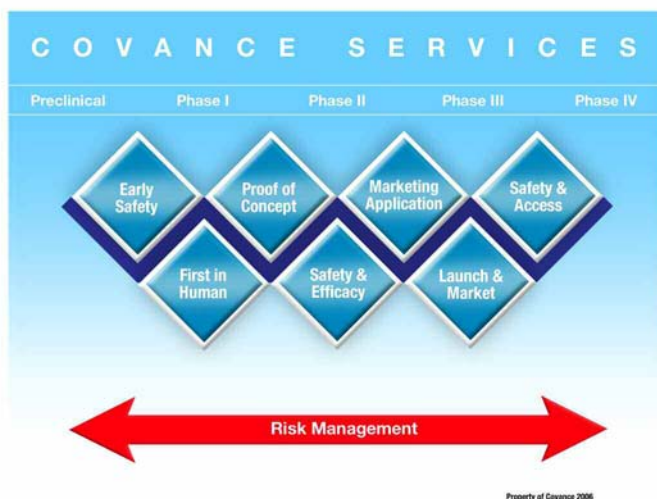
## **Development Goals**

As a global drug development services company driven by the pursuit of scientific, operational and service excellence, we can help you accomplish all of your drug development goals, including:

- Proving early safety
- Conducting a first in human study
- Conducting a proof of concept study
- Proving clinical safety and efficacy
- Filing for marketing approval
- Launching and marketing a drug
- Ensuring patient safety and access
- Managing risk

We focus on delivering high quality error-free data, meeting your timelines and providing exceptional customer service to advance your compound along the drug development continuum.

With our extensive expertise, resources and decades of experience, we can develop and execute a coordinated drug development program that efficiently and effectively advances your drug, with increased speed and quality. This streamlined approach is designed to help bring your drug to market as quickly, safely and cost-effectively as possible. In the pages that follow, we provide an overview of how our services can help you overcome your critical drug development hurdles.



**You can access all of the services you need to support your drug development – through the industry's most comprehensive portfolio of drug development solutions – from preclinical through commercialization.**

I need to...

## *Prove Early Safety*



Advancing your new molecular entity through preclinical development can be challenging. Doing so quickly and within your tight budget constraints can make it even more difficult. Whether you need just one study or a full portfolio of nonclinical testing services, we can help you accomplish your goals. Our comprehensive Program Management Services are available to serve as your tactical, logistical, and scientific interface to our global drug development resources. Our experienced staff can help you through the maze of early drug development. With our proprietary data management system, StudyTracker<sup>®</sup>, we keep you informed every step of the way as we work to help you meet your early development goals.

### Program Management Services

Our full-time program management team can help you to tailor a strategic and tactical drug development plan, designed to help manage your drug through proof of concept studies, based on your goals. The team will provide you with a single point of contact to integrate activities and ensure your preclinical plan supports your clinical goals.

Services include:

- IND/CTA enabling services
- Phase I first in human studies
- Phase IIa proof of concept studies

## *Nonclinical Services*

### Bioanalytical Chemistry

- Method development, transfer, & validation
- Organic synthesis
- PK analysis

### Biopharmaceutical Specialist Services

- Cell banking & biosafety
- Protein & immunochemistry
- PCR

### Drug Metabolism

- Discovery screening programs
- In vitro/in vivo GLP ADME studies

### Toxicology Services

- Genetic & molecular toxicology
- General & safety pharmacology
- IND/NDA enabling toxicology
- Oncogenicity
- Reproductive & developmental toxicology
- Specialty toxicology

### cGMP

- Batch release
- Method feasibility, development & validation
- Specialty services
- Stability studies

### Research Products

- Boarding services
- Purpose-bred research models

### Antibody Products and Services

- Custom immunology services
- Innovative antibody products

We leverage our nonclinical services and regulatory expertise to build a development program customized to your compound.



I need to...

## *Conduct a First in Human Study*

### *Phase I Services*

#### **Clinical Pharmacology Services**

- Drug/drug interaction
- First in human studies
- Pharmacodynamics
- Pharmacometrics
- Radiolabeled AME
- Single & multiple dose tolerance escalation

#### **Cardiac Safety Services**

- Collection, centralization, interpretation, storage & retrieval of data
- Definitive QT studies
- Electrocardiogram (ECG) testing
- Non-invasive cardiac monitoring

#### **Pre-Market Risk Assessment**

- Continuous modeling and program evaluation
- Evidence-based risk identification and monitoring
- Risk prediction

#### **Central Laboratory Services**

- Extensive test menu and validation of new tests
- Global automated kit production
- Global logistics support services
- Near real-time data access with LabLink™

In Phase I, your drug is introduced for the first time into humans, usually healthy volunteers. We know it is important for you at this point to identify any weak drug candidates to avoid unnecessary expenditure of time and resources and to minimize patient risk. To support these critical go/no-go decisions and to meet all of your early clinical development needs, we provide a full array of services, including **Clinical Pharmacology, Cardiac Safety, Risk Management and Central Laboratory Services.**

#### **Definitive QT Studies**

Recent ICH regulations require definitive QT studies to assess the repolarization effects of most new pharmaceutical agents, and regulatory agencies have heightened awareness of the potential adverse cardiac effects of new drugs. Thus, you will benefit most by working with an experienced drug development services company that offers scientific cardiovascular knowledge and a full breadth of services. At Covance, we offer a comprehensive set of cardiac safety services, and our people have the medical and scientific expertise needed to satisfy your needs in protocol design, conduct and interpretation.

Specifically, we can provide:

- Expert cardiac consultancy from initial study design through the final stages of data analysis and NDA submission
- The highest quality of ECG interpretation from our renowned Cardiovascular Sciences Team and network of Board Certified Cardiologists
- Knowledgeable clinical trial operations management dedicated to meeting your study requirements and timelines

You will benefit from the most reliable, precise cardiac safety data – through our Digitography™ technology which provides ECG waveform measurement down to one millisecond resolution.

I need to...

# Conduct a Proof of Concept Study

At this stage of drug development, Covance knows how important it is to obtain the necessary patient safety and efficacy data on your drug in a timely manner. To accomplish this, we tightly manage the laboratory testing, data collection and clinical trial of your drug as we help you with your Phase II/proof of concept study – from trial design and implementation to comprehensive laboratory testing and data management. We also help you begin risk minimization planning to ensure patient safety and manage risk.

## Virtual Central Laboratory<sup>SM</sup>

When your study requires a faster specimen testing turnaround time than is possible with a central laboratory, such as with oncology and critical care studies, or you need to collect specimens from difficult-to-access remote regions of the world, Covance VCL<sup>SM</sup> services can provide you with the next best alternative for collecting high-quality laboratory data. Covance VCL provides:

- Near real-time data collection in one global database to speed access to patient safety data
- Expanded access to treatment-naive patients from remote regions of the world
- Faster transfer of one global combinable dataset from local and regional laboratories to support successful product submissions

## Phase II Services

### Phase IIa/IIb studies

- Trial design, execution & analysis

### Global Project Management

- E-filing of your regulatory submission
- Investigator services
- Site selection & support
- Trial monitoring

### Central Laboratory Services

- Extensive test menu and validation of new tests
- Global automated kit production
- Global logistics support services
- Near real-time data access with LabLink

### Virtual Central Laboratory

- Centralized global data collection from local or regional laboratories

### Pharmacogenomics

- Clinical trial genomic microarray testing

### Cardiac Safety Services

- Collection, centralization, interpretation, storage & retrieval of data
- Electrocardiogram (ECG) testing
- Non-invasive cardiac monitoring

Every step of our process is designed to deliver fast, high-quality data, from the protocol and visit-specific patient kits to our global automated technologies for collecting specimens, result reporting, and data transfer.



I need to...

# *Prove Clinical Safety and Efficacy File for Marketing Approval*

## *Phase III Services*

### **Risk Management**

- Upfront proactive/preventive measures to ensure patient safety and manage risk

### **Phase IIIa/IIIb Studies**

- Trial design, execution & analysis

### **Drug Safety**

- Patient safety surveillance services
- Electronic diaries & registries

### **Economic Market Consulting**

- Reimbursement assessment & economic strategies
- Outcomes research

### **Central Laboratory Services**

- Extensive test menu and validation of new tests
- Global automated kit production
- Global logistics support services
- Near real-time data access with LabLink

### **Virtual Central Laboratory**

- Centralized global data collection from local or regional laboratories

### **Interactive Voice Response Services**

- Support for electronic patient-reported outcomes, drug inventory management, and patient enrollment and randomization

We know the stakes are rising in Phase III. There is pressure to substantially increase the number of trial participants, and there are constraints on patient accrual outside of Western markets - making regulatory approval more challenging. How can you assure appropriate product characterization and gain exposure to future prescriber targets while controlling escalating expenses?

At Covance, we help you succeed every step of the way through comprehensive clinical trial, execution and analysis services, including complete data management. With the experience of working on more than 15,000 clinical trials worldwide, we can help you substantially increase the understanding you derive from each phase of drug development. We can also help prepare and file your regulatory application and optimize the commercial potential of your drug.

## **Trial Assurance: A Focus on Prevention**

Did you know that remediation—fixing data problems after they occur—eats up 27% (and counting) of the average trial budget, delaying your trial and threatening your data quality? This is more than what is spent on the investigators who stand on the front line of your drug's success. And it is nine times more than what is spent on preventing the problems from happening.

Breaking the mold of the 'average trial', Covance places a unique focus on upfront due diligence and 'building quality' into your trial. This reduces trial delays and the time and resources spent to fix preventable errors. Our approach includes:

- Predictive feasibility and modeling for site selection
- Proactive project planning
- Clinical trial strategy focused on prevention of errors, versus a "find-and-fix" remediation approach

Your trial will run efficiently and effectively generating higher quality, on-time data – through our unique clinical development focus on predictive feasibility and modeling, proactive project planning and prevention of errors.

I need to...

*Launch My Drug*

*Ensure Patient  
Safety and Access*



At this stage of drug development, sponsors are concerned about satisfying postmarketing commitments and generating market uptake for their drug, while ensuring patient safety. To help you achieve these goals, we can help you predict potential issues that might challenge your drug's performance in the marketplace, and we offer a variety of post-approval programs to support the achievement of its full potential. Our Phase IV studies, postmarketing commitment services, patient and provider support programs, and product marketing services help put your drug in the hands of health care providers and patients who need it.

### Postmarketing Surveillance Programs

We can help you fulfill postmarketing commitments and regulatory obligations from pharmacology and toxicity through pharmacovigilance. Our customized services provide the valuable information you need to gain competitive advantage and to optimize your product's potential in the marketplace.

Our solution set includes:

- Flexible registries
- Creative, cost-effective phase IV studies
- Custom, value-added data solutions
- Observational monitoring of patient usage
- Comprehensive risk management programs
- Toxicology, pharmacology and other services

## *Commercialization and Risk Management Services*

### Phase IV Studies & Registries

- Safety studies
- Product and disease registries
- Health economic studies

### Reimbursement Consulting

- Reimbursement strategy for new products

### Postmarketing

- Market analysis
- Economic marketing strategies

### InTeleCenter® Contact Center

- Reimbursement hotlines
- Patient assistance & adherence programs

### Outcomes Research

- Studies that measure & document patient-reported benefits

### Risk Management

- Comprehensive risk minimization (RiskMAP) and pharmacovigilance programs

Your product will be put in the hands of patients that need it so it can achieve its full market potential – through our comprehensive marketing intelligence, economic marketing, customer support and Phase IV programs.

From preclinical development through drug commercialization, we can serve all of your drug development needs. For your program, we can leverage our extensive global presence around the world, broad therapeutic expertise and experience, and large base of over 7,000 dedicated employees to meet or exceed your business goals.

Let us put our people, processes and resources to work for you to help bring your miracles to market sooner. Contact your Covance representative for more specific information, or visit us at [www.covance.com](http://www.covance.com).



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