

Trust in the strength
of our **science**



p^ra

PRA International

THE GRO THAT UNDERSTANDS ENDPOINTS ■

Leading the way

with science and therapeutic expertise

At **PRA**, we pride ourselves on leadership. We're a Clinical Research Organization known worldwide for our therapeutic excellence in oncology, CNS, cardiology, respiratory and infectious disease.

Our scientific and medical experts, recognized throughout the globe as thought leaders, are members of advisory boards and published in leading journals. Their stature in the field and their extensive experience in clinical research are the foundation upon which **PRA** has built its trusted reputation.

We have more than 25 years of experience executing clinical research services for pharmaceutical and biotechnology companies. **PRA** offers a full range of services for **Early Development, Product Registration** and **Late Phase** research.

Our growing worldwide staff of more than 3,600 employees supports our operations on six continents. Operating from a common, global technology platform that maximizes resource efficiency and client access to data, we can take your molecule full cycle, from **first-in-human studies through approval and ongoing safety monitoring and post-marketing studies**.

*That's **PRA** International.
You can trust in the strength
of our science.*



THE CRO THAT UNDERSTANDS ENDPOINTS ■

Proven Therapeutic Leadership

Oncology

Since 2003
More than

300 Studies
1,200 Sites
115,000 Patients

PRA is a proven leader in oncology clinical drug development, with extensive involvement in the successful approvals of major life-extending cancer drugs. We provided the developers of such important cancer treatments as Sutent®, Nexavar®, Avastin®, Tarceva® and Velcade® with the full range of development and research services to accelerate their products to market.

As a leader in oncology, **PRA** has significant experience in many indications, with considerable expertise in non-small cell lung cancer, colorectal cancer, breast cancer and renal cell cancer.

Our strategic alliances with the Geriatric Oncology Consortium, US Oncology and IntrinsicQ expand **PRA's** ability to conduct accurate feasibility, accrue oncology patients, achieve faster study start-ups and potentially accelerate the development life cycle.

■ **PRA and US Oncology** aligned our processes with a focus on accelerating the clinical development lifecycle and delivering efficient service. US Oncology is a large network of 200+ community-based oncology centers staffed by experienced investigators. The network provides PRA access to a pool of 1,000 US oncologists and nearly 250,000 new cancer patients yearly, as well as thought leaders who augment PRA's therapeutic expertise.

■ **PRA** has exclusive access to the powerful patient treatment database **IntrinsicQ Research** that covers drug therapy administrations to more than 100,000 oncology patients in more than 600 practices in the US. It provides longitudinal chemotherapy records for over 45,000 cancer treatments per month that are based on actual treatment data rather than physician recall.

CNS

Since 2003
More than

270 Studies
11,000 Sites
59,000 Patients

We have extensive experience in several indications, with a focus on vascular dementia/Alzheimer's, epilepsy, ADHD, multiple sclerosis, pain and Parkinson's disease. The novel ADHD transdermal patch, Daytrana®, came to market in the US in 2006 after **PRA** provided the sponsor full clinical support from Phase I trials through product registration. Our neurobehavioral specialists conduct complex, neurobehavioral assessments employing effective, consistent and relevant rating scales.

Respiratory/ Allergy

Since 2003
More than

100 Studies
3,500 Sites
28,700 Patients

PRA is a prominent leader in clinical research for respiratory/allergy drug development. We provided the pivotal clinical services that led to the 2006 regulatory approval of fluticasone propionate nasal spray, the first generic nasal allergy spray to be approved by the FDA. We have extensive experience in asthma, allergic rhinitis and COPD.

Cardiovascular

Since 2003
More than

150 Studies
5,500 Sites
45,600 Patients

Within the field of cardiology, we have extensive experience conducting complex pivotal studies in niche indications like pulmonary arterial hypertension, venous thromboembolism, coronary artery disease, peripheral arterial occlusion and hyperlipidemia. Our cardiovascular experts regularly engage sponsors to assist in clinical program development, study design and agency interactions.

Infectious Disease

Since 2003
More than

90 Studies
1,400 Sites
63,800 Patients

Infectious disease rounds out our core therapeutic areas, with over a third of **PRA's** project management and clinical operations employees having experience in infectious disease research. Since 2003 **PRA** has conducted trials in more than 35 indications including hepatitis (20 studies), as well as extensive experience in vaccine studies of which almost 65% have been in infectious diseases



Early Development Services (EDS)

PRA has conducted **over 1,500 Phase I and IIa studies** for almost every major pharmaceutical company in Europe, the US and Japan, as well as many renowned biotech companies. Clients can “Find Out Fast” by taking a molecule from first-in-human to proof-of-concept through our clinical and bioanalytical laboratory facilities in the Netherlands and the US.

Clinical Services

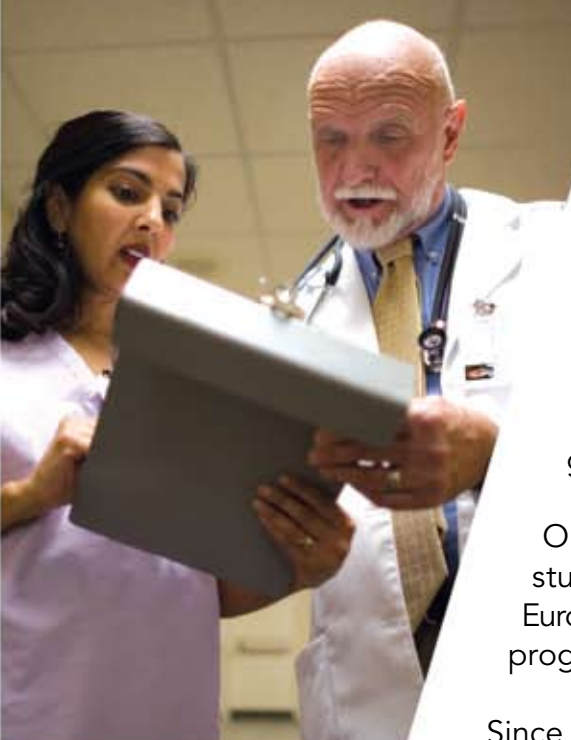
Pioneers in the use of microdosing, we specialize in the more complex first-in-human studies and studies with delicate safety pharmacokinetic or pharmacodynamic objectives, using extensive methodologies that we developed. In addition, **PRA** in the Netherlands provides an **advantageous regulatory environment**, including a 14 day approval timeline. Our IEC (BEBO) has committed to match the **approval timeline** set by Dutch law for the Competent Authority of **14 days** which matches the approval timelines for most US IRBs. With nearly 228 beds in the US and Europe, including a university hospital-based 70-bed unit, we have experience in a wide range of therapeutic areas with specialized expertise in respiratory and metabolic/diabetes indications. Our GMP-licensed, in-house pharmacy is also licensed to handle radiolabeled and narcotic medications.

PRA EDS also offers wider access in Central and Eastern Europe to ill patients who might otherwise be difficult to reach. This includes patients with renal and hepatic diseases as well as a wide range of other conditions.

Bioanalytical Laboratory Services

Our GLP-compliant Bioanalytical Laboratory in the Netherlands has hosted more than **2,400 studies** in the past 22 years. Outfitted with state-of-the-art equipment, it includes facilities for mass spectrometry (LC-MS), biochemistry & immunochemistry, mass balance studies and genotyping. To date, we have experience with more than 500 validated chromatography methods and more than 250 validated biomarker methods. The laboratory is certified for radioisotope analysis and the handling of biohazard samples.





Product Registration

Product Registration represents the core of **PRA's** business focus. In just the past 4 years, we have been instrumental in **helping sponsors achieve more than a dozen drug approvals**, including targeted therapies for oncology, CNS, respiratory/allergy and gastroenterology and a blood biologic for immunology.

Our global footprint allows us to conduct Phase II and Phase III studies in more than **60 countries** in North America, Latin America, Europe, Asia, India, Africa and Australia, and facilitates access to specific, program-driven patient populations.

Since 2006, **PRA's** Product Registration group conducted over 500 studies involving 20,000 sites and over 125,000 patients.

We offer the full spectrum of clinical development services, including:

- Feasibility Analysis
- Regulatory Affairs
- Study Start-up
- Investigator Recruitment and Relations
- Patient Recruitment
- Clinical Monitoring and Site Management
- Data Management, including electronic data capture
- Analysis & Reporting
- Submissions Management

PRA has the capabilities, experience, and resources to provide comprehensive project services to our clients to ensure program success. At **PRA**, every project team is supported by a company-wide commitment to their success.





Late Phase Services

Our Late-Phase Services group supports global and regional Post-Approval studies. Late-Phase Services assists sponsors with the Post-Marketing process by planning and conducting Safety-Surveillance studies, Large Simple Trials (LSTs), Registries, Retrospective Studies and Restricted Access Programs. Our international management team has many years experience managing late-phase studies ranging in size from 60 patients to 18,000 patients. The Late-Phase Services operational team is supported by **industry-leading strategic, scientific, medical, and epidemiological experts** who collaborate with sponsors to design and implement **outcome-driven** process and data collection strategies.

- Safety Surveillance/Post-Authorization Safety Studies (PASS)
- Large Simple Trials (LSTs)
- Disease/Product/Pregnancy Registries
- Restricted Access Programs
- Retrospective Studies

Services That Support Clinical Development

PRA provides the functional support services you need in a partner to support your drug development efforts. From our roots as a data management company more than 25 years ago, we endeavor to meet your needs from study start to finish.

Therapeutic Expertise

PRA's Therapeutic Expertise group is home to a highly respected group of in-house experts, many of whom are board certified. These professionals provide services through all phases of drug development. They have built **strong relationships with clinical investigators worldwide** and know where to find the specific target populations for your studies. Their in-depth feasibility assessments reduce your risk and increase the likelihood for study/program success.

Safety & Risk Management

Our physicians, epidemiologists, pharmacists, statisticians, clinical programmers, safety specialists and research nurses are available to ensure that safety procedures are followed and **adverse events are handled properly**. *In 2007, PRA processed more than 14,000 Serious Adverse Events and distributed nearly 40,000 safety letters.*

Regulatory Affairs

PRA, as your regulatory partner and consultant, is focused on expediting the regulatory review process and **shortening drug development timelines**. We offer regulatory support for Marketing Authorization and Clinical Trial Applications and can assist you with strategic regulatory consultation throughout the drug development process.

Submissions Management

PRA's Submissions Management group provides a full spectrum of comprehensive services and expertise. **PRA's** experience enables us to more effectively partner with our clients in the preparation of quality marketing authorization submissions. Services include project management, data integration and analysis, medical writing, regulatory consulting, and publishing. For the marketing authorization submission, **PRA** has capabilities ranging from rapid production of paper-based submissions to expertise in electronic submissions publishing.

Data Management

PRA provides global Data Management services through integrated, industry-leading platforms. These data solutions combine electronic data capture and paper data management in easy-to-use hybrid systems, backed by a comprehensive support structure. Our 300+ Data Management professionals, working from **four Data Management hubs** strategically placed around the globe, are prepared to handle high volume throughput and meet emerging study needs **24/7**, including **continuous data processing**.

Analysis & Reporting

Depend on **PRA** to **provide seamless Analysis & Reporting** services—with a strong emphasis on client focus and delivery. Across the globe we employ over 130 highly skilled biostatisticians, analysis programmers and medical writers to meet your needs.

At **PRA** we pride ourselves on the quality of our medical writing team, most of whom have doctoral degrees and many years of experience. Our rigorous quality procedures ensure that our scientific documents meet the highest standards.

Quality Assurance

PRA maintains an **independent global Quality Assurance team** of experienced professionals in North America and Europe. Our QA auditors perform audits on behalf of clients on all the processes used in the management of clinical trials at all project stages.



Getting it right

At PRA, our scientific strength is your advantage. We offer a unique combination of therapeutic excellence and clinical experience that is essential to the development of your drug. We work with you as a collaborative partner throughout the project lifecycle, always with your endpoints in mind. You can trust us to get the details right, from start to finish, every step of the journey. That's our promise to you and we deliver on it every day.

World Headquarters

PRA International
Glen Lake 4
4141 ParkLake Avenue, Suite 530
Raleigh, NC 27612 USA
Tel: + 1 919 786-8200
Fax: + 1 919 786-8201

To learn more, e-mail us at endpoints@praintl.com
or visit www.prainternational.com

© Copyright 2008 PRA International. All Rights Reserved



THE GRO THAT UNDERSTANDS ENDPOINTS ■

