

## bioRASI, a full service global CRO.

Specializing in ANDA and 505(b)(2) NDA programs, bioRASI obtains FDA approvals by delivering high quality regulatory and clinical strategies, solutions and services, while saving their clients critical time. bioRASI services include program management, regulatory, clinical, data management and analysis, compliance and audit. bioRASI leverages its access to well renowned researchers and facilities, in the U.S., Europe and Asia, to achieve unparalleled scientific, clinical and business results at significantly lower costs. bioRASI is headquartered in Hollywood, FL and has regional offices, labs, and clinics across the globe.

bioRASI's  
Moscow  
Headquarters

### bioRASI

#### U.S Locations

- ❖ Miami
- ❖ Los Angeles
- ❖ San Diego
- ❖ Charlotte



#### Overseas Locations

- ❖ Moscow
- ❖ Kiev
- ❖ Belgrade
- ❖ Riga
- ❖ Mumbai

### The Russian Academy of Science

bioRASI, a US-based company, initially formed as a strategic initiative of the RAS, has grown into a world-wide CRO. The Academy was founded by Peter the Great in 1724 and now embodies around 250,000 scientists in more than 900 institutes and clinics. The Academy is one of the most respected R&D institutions in the world, currently performing more than \$2B in commercial contracts for private companies, governments and NGOs worldwide. bioRASI has leveraged hundreds of RAS's researchers and investigators in its contracts with global firms and Pharma leaders worldwide. Sponsors of all sizes choose the Russian Academy of Sciences Initiative, bioRASI, to gain competitive advantage through its renowned expertise and infrastructure.

- 🔍 **bioRASI is your experienced partner in global generic trials**
- 🔍 **bioRASI has access to required subjects pools including special population**
- 🔍 **bioRASI offers complete range of services for ANDA and 505 (b) (2) NDA submissions**
- 🔍 **bioRASI enjoys special access to experienced investigators and FDA- Audited Sites**

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# bioRASI

## ANDA and 505(b)(2) NDA Programs From A to Z

# bioRASI

Helping clients to lower costs and expedite  
ANDA and 505 (b)(2) NDA Programs

### Focus , Understanding, and Experience

Our focus on generics and specialty pharmaceuticals enables us to understand the competitive and regulatory challenges that are unique to the industry. Price erosion due to competition and increasing delays in FDA approvals are creating continuous pressure on profit margins. bioRASI can help: faster development and lower costs. With the experience of managing dozens of ANDA and 505b2 programs in the past few years, and a particular strength in clinical endpoints or special population PK trials, bioRASI is well positioned to get your program to and through the FDA approval in record time.

### Full Service Offerings

We handle the entire range of ANDA and 505 (b)(2) NDA programs, from program management and regulatory strategy through clinical services, data management, statistical analysis, report writing and filing.

### Global Reach, Top Researchers, and Lower Costs

As a global CRO, we not only have access to researchers and facilities in the US and Western Europe, but also to the finest researchers and facilities in Eastern Europe, India and Russia where the science is first rate at significantly lower costs. This global reach also allows us the flexibility to run trials simultaneously all around the world.

# bioRASI

Where CRO really stands for Clinical  
Research Optimized

### ANDA and 505(b)(2) NDAs Fast Growing Segments

Over the next 10 years, the generic (ANDA) industry will grow at 10% per annum globally. In the U.S. market alone, \$143 billion in branded sales are projected to go generic during this period, which will translate into \$23 Billion in new generic drug sales. Meanwhile, the pipeline of New Molecule Entity (NME) NDAs continues to wane. Of 93 NDA approvals in 2006, only 18 were NME drugs. More than twice that number, or 40% of the total, were 505(b)(2) NDAs representing drug delivery or formulation enhancements or combinations.



## Competition and Regulatory Challenges

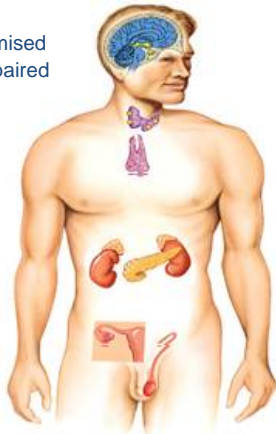
Generic drug companies are experiencing increased competition and consolidation. Forty four firms had first ever product approvals over the past 2 years. New entrants breaking into the U.S. Generics market will sell against entrenched competition with low cost of capital and global manufacturing resources. Profit margins are under continuous pressure as competition drives price erosion in the base businesses.

Approvals are taking longer and longer which causes significant impact on projects. In 2007 there were 880 ANDA filings with only 494 approvals. For 2008, more than 830 ANDA filings are projected. Approval times are averaging 18 months and 73% of approvals and filings have a 2 year review period.

### bioRASI's Unrivalled Access to Subjects:

- Healthy Volunteers
- Special Patient Populations

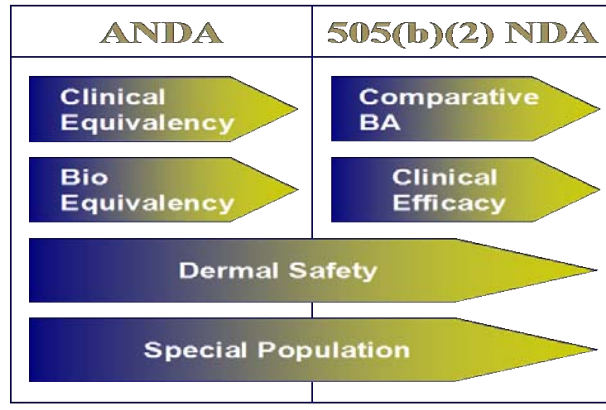
- Hypogonadal men
- Post-menopausal women
- Endocrine abnormal
- Treatment naïve HIV
- Asthmatic
- Psoriatic
- Amyotrophic Lateral Sclerosis
- Immune Compromised
- Hepatic, renal impaired
- Schizophrenic
- Epileptic
- Ulcerative colitis
- Hypertensive
- Cancer



## bioRASI Generics Division

### ANDA and 505(b)(2) NDA

From  
**Program Management and Regulatory Strategy**  
to  
**Clinical and Analytical Services**  
to  
**Data management, Analysis and Report Writing**



Development of the generic drugs for ANDA or a new formulation of the approved drugs for 505(b) (2) NDA submissions is a complex process requiring a combination of program management and regulatory strategy, clinical and analytical testing, data management and technical writing. bioRASI provides its clients with all, or any combinations of the required assistance. bioRASI has the following service branches to accomplish its clients needs:

- Program Management
- Regulatory
- Clinical
- Data Management and Analysis
- Compliance and Audit

bioRASI's expertise in ANDA and 505(b) (2) submissions helps its clients to reach positive outcomes expeditiously.

**bioRASI's patent-pending rater training methodology reduces the time and costs of the sponsors study by significantly reducing inter- and intra-rater variability**

## Clinical Equivalence

bioRASI has established itself as a leader in the area of Clinical Equivalence Studies. It is conducting CE studies in the USA, and around the world. We have selected and established special relations with over a hundred dermatology, gastroenterology and ophthalmology clinics. Those clinics established themselves as having the fastest recruiting in the world as well as highest quality results.



### BA/BE

bioRASI routinely conducts BE/BA studies on healthy volunteers but our unique strength is in our focus on studies with special population. Our potential subjects data basis contain hundreds of thousands of potential patients and special population participants. Our two clinic with combined capacity of over 200 beds strictly adhere to ICH/GCP standards and have the ability to accommodate trials on very short notice.

### Clinical Efficacy

The bioRASI US and Global Infrastructure has been involved in conducting clinical trials in numerous indications, some of them with therapy naïve patients (when required). The patient flow in the clinics that bioRASI uses is arguably the highest in the world. All of this allows for the fast recruitment and protocol fulfillment in your clinical trial.

### Dermal Safety

bioRASI has emerged as the leader in clinical development of transdermal products. We perform both PK and dermal safety studies. We often combine dermal irritation, sensitization and patch adhesion studies in one, saving costs and valuable time.