



Industry Sensitive, Academically Based

**A New Model for Clinical Research
in the Heart of Manhattan**



research

The Bluestone Center for Clinical Research at New York University is a contract research organization (CRO) dedicated entirely to the development, implementation, performance, and analysis of clinical research in an environment that combines academic excellence with industry's efficiency and speed.



The mission of the BLUESTONE CENTER is to:

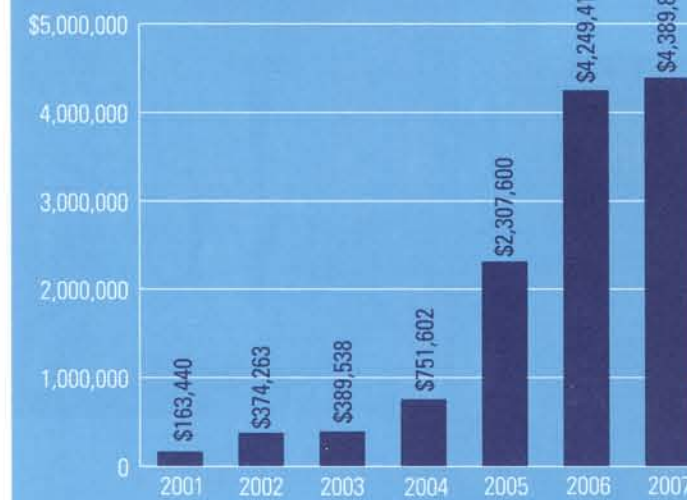
- *conduct research that generates and applies biomedical, behavioral, and clinical knowledge and technology to health and disease*
- *promote the transfer of knowledge and technology to clinical care*
- *impact health globally through clinical research*

The Bluestone Center is the only non-NIH-funded, academically based, general clinical research center in the United States. The Bluestone Center conducts NIH-, industry-, and foundation-sponsored medical and dental investigations — phase I-IV pharmaceutical, biotech, medical and dental device studies — accommodating both outpatient and overnight studies according to GCP principles and in accordance with all OHRP, FDA, and HIPAA regulations.

The Bluestone Center is fortified by a unique set of assets.

- At 8,585 square feet, the Bluestone Center is the largest clinical research center of its kind in the United States.
- In contrast to the majority of NIH-funded centers, the Bluestone Center has no limit on the number of industry-sponsored trials it can conduct.
- While most academically based clinical research centers share staff resources, the Bluestone Center has its own comprehensive, dedicated staff.
- Unlike other clinical research centers, the Bluestone Center, as part of New York University — a research-one university— is capable of disseminating results globally through an international alumni network numbering in the tens of thousands and an unequaled network of international research partners.
- Located in the heart of ethnically diverse Manhattan, the Bluestone Center is able to recruit the largest, most diversified patient population in the nation for every conceivable clinical investigation.

TOTAL BCCR FUNDING FROM 2001-2007



*Committed funding for 2007

Since opening in 2002, the Bluestone Center has conducted over 50 studies grossing more than \$10.9 million in research-related revenues. The Bluestone Center is also the site of a \$26.7 million, seven-year NIH-funded grant to establish a regional, practice-based research network, the PEARL Network, or Practitioners Engaged in Applied Research and Learning. The PEARL Network links private dental practices together to conduct clinical research aimed at enabling greater scientific rigor to be brought to "everyday" issues in the practice and delivery of oral health care.

assets

mission



Based at New York University, the Bluestone Center for Clinical Research was created in response to the need for a clinical research center capable of conducting both industry-sponsored and NIH-funded clinical trials with consistently on-time, quality-assured outcomes. The Bluestone Center's ability to mobilize all resources strictly for clinical research activities provides a competitive advantage over most academic investigators and private research organizations.

Viewing synergy as a strategic goal, the Bluestone Center has built teams of first-rate NYU research and clinical experts, who work together in an environment in which interaction and cross-pollination of ideas can flourish. What makes this environment unique is a business management perspective that emphasizes sensitivity to the needs and time demands of industry.



Each potential study at the Bluestone Center is evaluated by an Executive Committee of qualified professionals with different areas of expertise. Research projects conducted at the Bluestone Center are based upon scientific credibility, research relevance, availability of adequate resources and equipment, potential to recruit and retain research subjects, and cost.



"At the Bluestone Center, we understand that rigorous attention to key issues such as protocol design, research standardization, research training, uniform performance measurement, workflow enhancements and improved patient recruitment are key to accelerating clinical trial timelines."



Jonathan Ship, DMD, FDS, RCS
Director

Dr. Ship leads and approves research strategies, reviews projects, advocates for the center's issues, including adherence to good clinical practice (GCP) guidelines, and helps set the overall direction of the organization.

Dr. Ship is a clinical researcher and expert in oral medicine with a 20-year history of funded research. He is a Professor, in the Department of Oral & Maxillofacial Pathology, Radiology and Medicine (NYU College of Dentistry), and a Professor in the Department of Medicine (NYU School of Medicine). He is also the Principal Investigator of a \$26.7 million, seven-year NIH-funded dental Practice-Based Research Network (PBRN) grant.



Patricia Corby, DDS, MS
Assistant Director

Dr. Corby heads the Bluestone Center Trials Executive Team, guiding development, research training, and updating of all Standard Operating Procedures (SOPs); overseeing the use of technology and information management to promote patient care and research; analyzing clinical research informatics needs; developing design options to support clinical research; and implementing and evaluating responsive clinical information technology solutions to support research projects. She is an Assistant Professor at NYU with an MS degree in Biomedical Informatics and over 10 years' experience in designing, conducting, and monitoring clinical trials and biomedical research.



Derek Grimes, BS
Executive Administrator

Mr. Grimes is the Executive Administrator of the Bluestone Center and has over 8 years' administrative experience with NIH- and industry-sponsored clinical research. Mr. Grimes oversees all contractual, budgetary, and Bluestone Center administrative functions. The Office of the Executive Administrator also prepares standard budgets, letters of understanding, confidentiality forms, contracts, and regulatory forms for all clinical research investigations at the Bluestone Center.



Frederick A. Curro, DMD, PhD
Director of Pharmacotherapeutic/Regulatory Research

Dr. Curro is the Director of Pharmacotherapeutic/Regulatory Research at the Bluestone Center. He is a clinical pharmacologist/regulatory and medical affairs specialist with over 30 years' experience in the pharmaceutical/biotechnology sector. He has conducted many phase I-IV clinical trials. Dr. Curro is a member of the United States Pharmacopeia Expert Advisory Committee on Dermatology and Special Populations/Clinical Pharmacology for 2005-2010.



Robert Norman, PhD
Director of Biostatistics and Data Management

Dr. Norman is a Research Associate Professor in the Department of Epidemiology & Health Promotion at NYU and Chief of Biostatistics and Data Management at the Bluestone Center. Dr. Norman provides guidance in research design, sample size estimation, development of statistical analysis plans, and implementation of those plans. Dr. Norman has extensive experience in both clinical research and biostatistics.

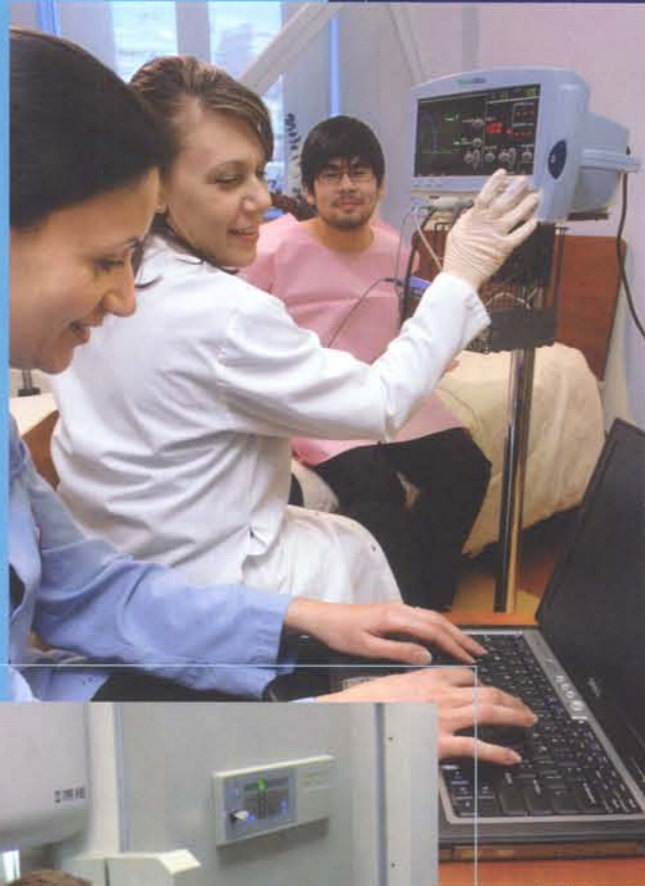


Margaret Andrew, RN, BSN
Chief Clinical Research Coordinator

Ms. Andrew is the Chief Clinical Research Coordinator at the Bluestone Center. She is responsible for overseeing all aspects of the clinical operation. Ms. Andrew has 13 years' experience in coordinating NIH- and industry-sponsored clinical trials, including site preparation, data collection, and CRF management, subject recruitment, and screening. She has 18 years' experience in providing direct patient care as a staff nurse in infectious disease and medical-surgical units.

The Bluestone Center is further strengthened by a dedicated, full-time staff, including:

- Research subject recruiter
- Nurse researcher
- Five clinical research coordinators
- Assistant biostatistician
- Data manager
- Assistant administrator
- IRB facilitator
- Quality assurance expert
- Research assistant
- Receptionist



facility highlights

The Bluestone Center's physical site and full-time staff provide the space, equipment, experience, assistance, and guidance necessary for time-sensitive, ethical, and high-quality research. Facility highlights include:

- Research-dedicated waiting room with three staff reception areas
- Four overnight suites with a total of eight beds, with cable TV, Internet access, and two beds per suite, primarily designed for phase I pharmacokinetic and pharmacodynamic research and for translational and sleep studies
- Nurses' station with central monitoring for the four overnight suites
- Secure drug, device, and medical equipment storage room
- Subject consent and education/questionnaire office
- Data storage facility for records and materials
- Day lounge, with cable TV and Internet access; convertible to an overnight bedroom for research personnel and clinical investigators
- Physical exam room
- Quality assurance office for visiting monitors (CRAs) and in-house QA personnel
- Administrative suite, with four offices, high-capacity color copier, and fax machine
- Office space for research recruiter, data manager, and biostatisticians
- 12-seat multimedia conference room
- Computers and clinical informatics support such as Electronic Data Capture, wireless Web-based connectivity, restricted access to research data
- Two surgical operatories for oral and maxillofacial surgery, dermatology, general and pediatric oral health research, physical examinations, and outpatient medical procedures
- Eight-chair dental operatory suitable for any dental/oral health investigation, equipped with digital intraoral radiology
- Radiology suite for digital extraoral radiography, including craniofacial spiral tomography
- Biological laboratory with refrigerated centrifuge, -86 degree Celsius freezer, general-purpose laboratory refrigerator/freezer, and an A/B3 biohazard hood
- Dental laboratory with two standing bench workspaces, each with suction, air and gas, deep sink, grinding machine, and lathe



The Bluestone Center has successfully completed phase I-IV industry-sponsored medical drug and device clinical trials in the following areas:

- Rx Pharmaceuticals
- OTC Pharmaceuticals
- Medical Trials
- Nursing Areas of Research



Rx Pharmaceuticals

Many of the clinical trials conducted at Bluestone are dedicated to new therapies in preparation for FDA submission and approval in accordance with the strictest government regulations and ethical guidelines.

OTC Pharmaceuticals

The main OTC (over-the-counter) pharmaceutical trials conducted at Bluestone are on analgesics (pain relievers), cough/cold/sore throat treatments, skin care treatments, and gastrointestinal products. Other OTC areas include vitamins and minerals, smoking cessation products, hay fever remedies, eye care treatments, sleeping aids, and medicated mouthwashes/sprays.



"We help companies take their drugs, biologics, and medical device products from bench to marketplace."

Medical Trials

- Sleep research
- Infectious diseases
- Biopharmaceuticals
- Neuropsychiatry
- Pregnancy, menopause
- Head and neck cancer
- Pain (acute and chronic)
- Dermatology
- Rheumatological diseases (Rheumatoid arthritis, osteoarthritis, SLE, Sjögren's syndrome)
- Organ transplantation
- Pulmonary diseases (asthma)
- Gastroenterology (reflux, heartburn)

Nursing Areas of Research

- Behavioral research
- Geriatrics and gerontology
- Quality of life
- Outcomes research
- High-risk pregnancy
- Sexually transmitted diseases
- Prevention and risk reduction
- Tertiary care



The Bluestone Center conducts phase I–IV, pharmaceutical, biotech, and dental device studies in the following areas:

- Oral fungal, viral, and bacterial infectious diseases
- Aging and geriatrics
- Dental caries, periodontal diseases
- Dental implants
- Oral cancer
- Saliva and salivary diagnostics
- Behavioral and sleep research
- Oral manifestations of systemic diseases
- Neurosciences, pain, and anxiety
- Dental biomaterials, products, devices
- Orthodontics
- Dental cosmetics
- Dentifrices, whitening, halitosis
- Oral mucosal diseases (aphthous stomatitis, herpes, pemphigus)
- Complete and partial dentures

The Bluestone Center's vision is to become the industry leader in conducting clinical trials and providing research services to investigators and sponsors.



Bluestone Center Administrative Functions Include:

- Standard budget preparation
- Confidentiality agreements
- IRB issues
- Regulatory services
- PMA/IND submission
- Contract agreements

Recruitment of Study Subjects

A full-time study subject recruiter is a member of each protocol team that includes the Principal Investigator and the study-dedicated clinical research coordinator (CRC).

A vast array of IRB-approved recruitment techniques are used in the Bluestone Center, and each study start-up includes a customized recruitment plan.



Clinical Monitoring

Bluestone Center personnel are experts in all aspects in the conduct of clinical research, using GCP guidelines, HIPAA regulations, and established rules of the New York University IRB, federal regulations, and NIH standards.

The Bluestone Center has standardized training and examination modules available on a Bluestone Center-dedicated intranet for all research personnel from volunteers to biostatisticians to principal investigators. Annual re-certification is required for all research personnel.

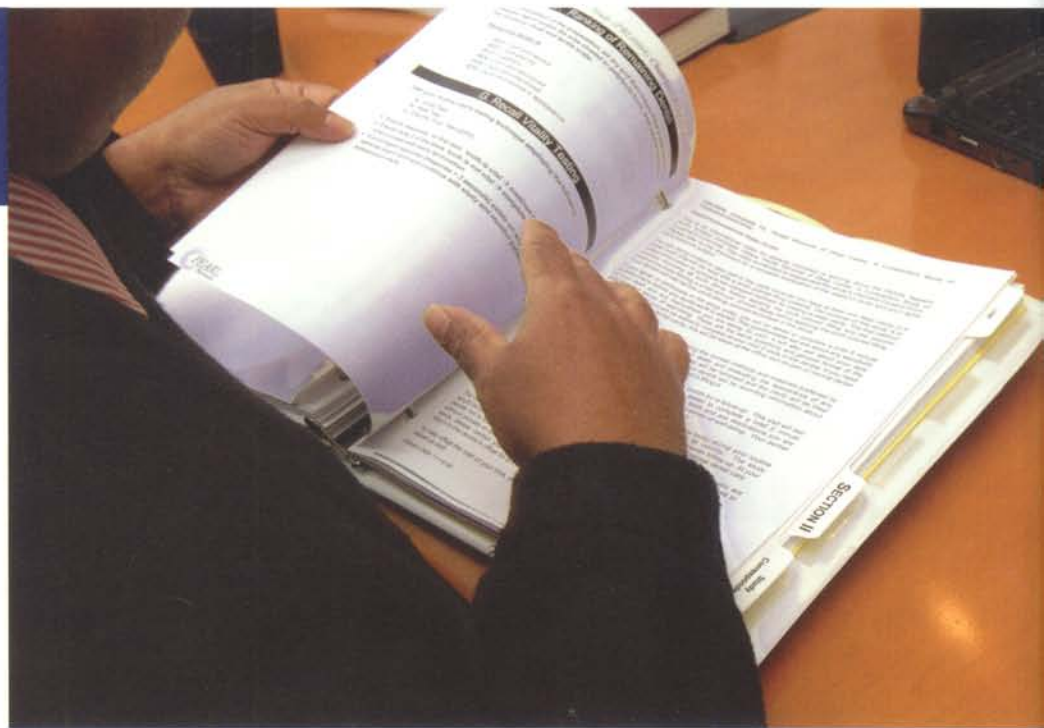
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Database Management and Statistical Analysis

At the Bluestone Center, a full-time director of Biostatistics and Data Management oversees a team of biostatisticians, data management experts, and data entry personnel.

All aspects of biostatistics are prepared for study protocols, and quality assurance is integral to all study-affiliated data. Expertise is available for all data management issues, including:

- Case Report Form (CRF) development
- CRF design and production, either paper or electronic
- Database design, construction, and qualification
- Data entry and verification
- Data cleaning
- Exportation of clinical database
- Database freeze, lock, and audit



Regulatory Affairs

The Bluestone Center has experience in partnering with start-up biotechnology companies in both clinical and regulatory affairs, preparing study documents, supporting FDA proposals, and assisting in the FDA-approval process. Our collaborative efforts start with study design inception and continue until final reports are prepared and presented to regulatory officials.

d a t a
m a n a g e m e n t

AAI International
Ace
Adams
Align Technology, Inc.
Amarillo Biosciences, Inc.
American Lung Association
Aspreva
Astra Tech AB
BioAlliance Pharma
BioDelivery Sciences
Biocosmetics
BioloK
Cadbury Schweppes
Captek
Celgene
CHPA Oral Discomfort Task Force
Colgate
CSI Biosciences
D4D / H. Schein
Daiichi Pharmaceuticals
Dentatus
Dentsply
Discus Dental
EOS
Fleminger, Inc.
GoSmile
Heraeus Kulzer
Hoffman-La Roche
Implant Innovations, Inc.
Innova
International Foods and Flavors
Inveresk / Flemming
Johnson & Johnson
McNeil Pharmaceuticals
MedImmune Oncology
MGI Pharma
Millennium
NIDCR, NIH
NCI, NIH
Nobel Biocare
Novalar Pharmaceuticals
Novartis
Ondine BioPharma
OraPharma
OraSure
Osteohealth
Panadent
Parkell
Pemphigus Foundation
Peptimmune Inc.
Pfizer
Phillips
Procter and Gamble
Quadex Labs
RAND Hartford Foundation
Rolly Brush
RxKinetix
SS White
Straumann
TolerRx, Inc.
Trigeminal Neuralgia Association
Violight
Zila Pharmaceuticals



NYU BCCR

BLUESTONE CENTER FOR CLINICAL RESEARCH

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