BRACANE COMPANY, Inc.

Research Organization delivering reliable, efficient and consistent service **since 2002**

Founder/CEO Bracane Company

Pamela Nelson, Ph.D., MSN

"Let's Shape the Future of Clinical Research Together."

Contact Information

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Reach Out for Collaboration and Excellence

Company Overview

Our Clinical Research Solutions

Bracane Company

- Provides outsourced clinical trial solutions to pharmaceutical companies worldwide
- Advance solutions for high quality and reduced trial costs
- Offers rescue services for challenged clinical projects

Our Key Capabilities

Full-Service Partnership (FSP)Model

- Collaborative, seamless research with flexible resourcing
- Cost-effective solutions from skilled professionals
- Benefits: Customized approaches, resource efficiency, and faster timelines

Clinical Operations

- Clinical operations excellence for success at every stage
- Protocol designing, site selection, and patient recruitment
- Innovative technology: BAISUS, KOL Mining, and Site Identification Platform

Clinical Monitoring Oversight

- Ensuring data quality and site compliance
- Approach: Risk-based monitoring and timely issue resolution
- Project rescue and data integrity assurance

Trial Management

- Seamless trial management from inception to completion
- Strengths: Consulting, project planning, budget management, and cross-functional coordination

About Us

- **Location: Plano, TX**
- **Scale: International**
- **Team Members: 14**
- **NAICS Codes: 541690, 541611, 541618, 541715, 541720**

Accomplishments:

- **DFW Minority Business. Development Council Supplier of the Year 2019, 2022**
- **Department of Commerce Award for Developing Trade**

Key Clients

Boston Scientific, BIO EYE, BlueCross BlueShield, EMERGENT, OC health CARE AGENCY, Reveles, Unilever, FedEx Express

Comprehensive Clinical Project Solutions

Our Approach: Rescuing trials and restoring confidence

Tailored Solutions: Custom Strategies

Expert Team: Power of Experience

Highlights

Comprehensive Assessment
- Identify issues
- Analyze data
- Evaluate processes

Data-Driven Solutions
- Correct course
- Mitigate risks
- Solve problems proactively

Multidisciplinary Experts
- Clinical operations
- Data management
- Regulatory compliance

Our Services

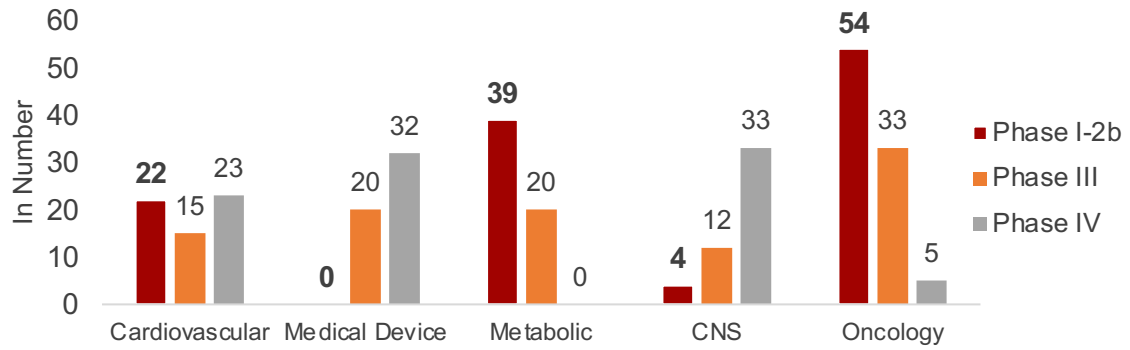
- Strategic assessment
- Rapid action plans
- Regulatory review
- Protocol amendments

Why Choose Clinical Project Salvage?

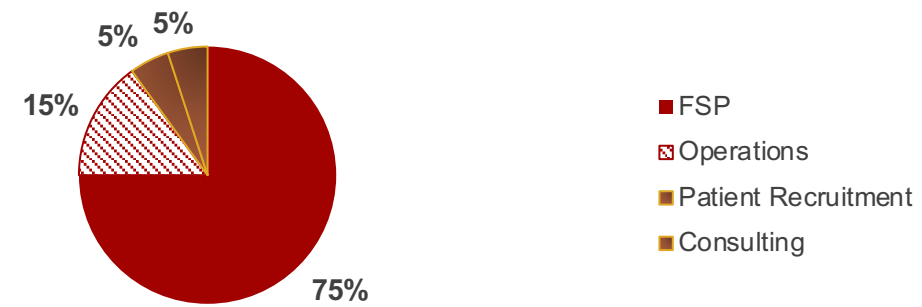
Swift, Effective, Reliable
- Save time
- Recoup investments
- Restore confidence

Performance Analysis

Project Distribution by Therapeutic Area



Service Delivery Breakdown



*FSP - Functional Service Provider

Why Partner with Us?

Reliability, Efficiency, Consistency

Tailored solutions	Industry expertise	Proven track record	Thought leadership	Resource and time savings

Key Differentiators

Efficient Project Management
- **On-Time Excellence**
  - Keep trials on schedule
  - Adhere to budget

Innovative Thought Leadership
- **Shaping Future Research**
  - Drive industry innovation
  - Stay ahead of trends

Maximized Savings
- **Time and Resource Efficiency**
  - Streamlined operations
  - Substantial cost savings

Reliable Partner for Success
- **Trusted Partner**
  - Navigate challenges
  - Deliver consistent results

Unwavering Efficiency Across Projects
- **Consistency in Every Endeavor**
  - Maintain efficiency
  - Handle project complexity

Success Stories

Case Study 1
Medical Device Study

Challenge
- Initiate 175-patient study
- Full-service project required

Solution
- Project management
- Clinical monitoring
- Database design

Outcome
- Sites opened in 60 days
- Study completed in 18 months
- FDA clearance obtained

Case Study 2
Compliance Audit for Biotech

Challenge
- Internal and site audits
- Re-review CT Scan data
- Assess AE/SAE reporting

Solution
- Clinical operations audits
- Gap analysis
- Mock audits and consultations

Outcome
- Issues identified and resolved
- Successful PMA completion
- 3 years support for additional studies

Case Study 3
Coordinator Placement Success

Challenge
- Hire onsite coordinator for client

Solution
- Hired experienced coordinator
- Coordinator offered FTE position

Outcome
- Expanded opportunities and task orders
- 4 placements since early 2023
- Revenue tripled since 2021

Clinical Trial Site Availability & Geographic Distribution

Key Highlights

- **150+ clinical trial sites** immediately available across the United States
- **Presence in 25+ states**, ensuring comprehensive coverage nationwide
- **Main Site Partners:** UTSW, Sara Cannon, Fred Hutchinson, Tranquil Research
- **CRO Support:** One Consortium (Pharmavise, Connexus, 2030 Consulting, CR Clinical)
- **Data Management, TMF, & CTMS:** Mediata Rave, Medrio, Cloudbyz

Geographic Distribution of Trial Sites

Region	Number of Sites
Northeast	30+
Midwest	40+
South	50+
West	30+
Total Sites	**150+**

Site Activation Process

Immediate Access to Sites
Partner sites are fully prepared for rapid activation

Customized Setup
Activation timelines are optimized with the support of experienced CRO partners

Streamlined Data Integration
CTMS ensure real-time data capture and site monitoring

Full Geographic Coverage
Activation across major clinical hubs with the flexibility to expand further as needed

External Test Platforms and Support for Commercialization

External Test Platforms

- **Compliance**
  - Many external tests are performed on In-Vitro Diagnostic (IVD) platforms
- **Certification**
  - Ensure that external laboratories use IVD-certified platforms that adhere to regulatory standards

Capabilities for Commercialization and Regulatory Approval

Regulatory Support

- **Regulatory Filing**
  - Assist with regulatory submissions (e.g., FDA, EMA) for test approval
- **Documentation**
  - Provide necessary documentation and validation data for regulatory review
- **Compliance**
  - Ensure adherence to regulatory guidelines for test development and commercialization

Commercialization Support

- **Market Access**
  - Assist with strategies for market entry and reimbursement
- **Quality Assurance**
  - Implement quality control measures to meet industry standards
- **Stakeholder Engagement**
  - Ensure successful test adoption and integration into clinical practice

Our Key Leaders

Cynthia Breeden-
Administration Project
Manager

Connie Taylor
Director Clinical Operations
Advisory Team

Evens Blanc
Government Clinical Operations

Mark Mohair
Professional Placements
Advisory Team

Claire Asogwa
Clinical Project Management
Advisory Team