

Patience In Patient Recruitment

Examining Current Challenges with Humans in Phase I Clinical Trials

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Workshop Agenda

- **First Half**
 - Current Challenges Identifying Subjects
 - Who Are the Ideal Patients?
 - Diversifying Patient Populations
 - Patient Recruitment Provider Solutions
 - Protocol Assignment for Second Half

Workshop Agenda

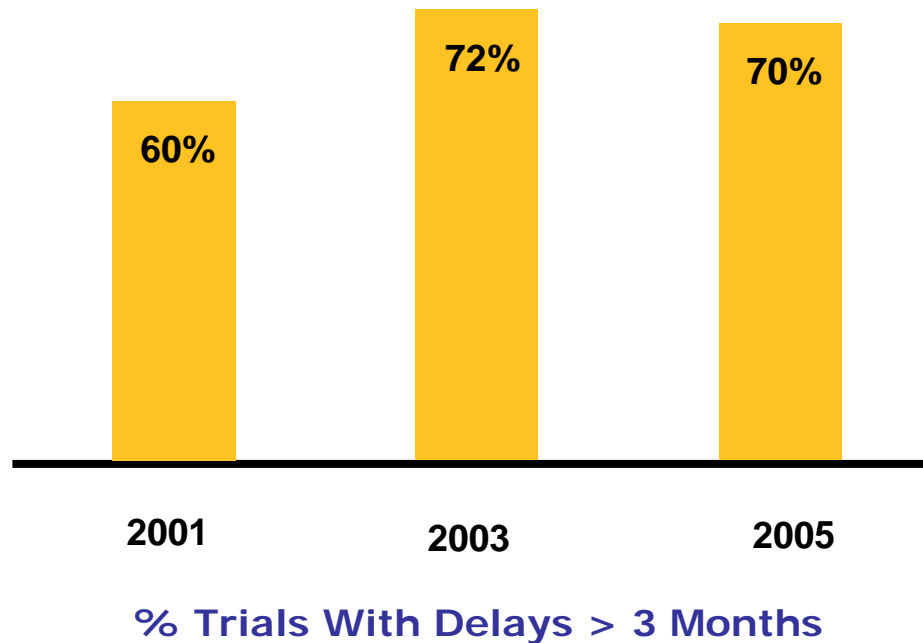
- **Second Half**
 - Creating the Solutions
 - Sharing Your Patient Recruitment Plans
 - Questions & Answers

Current Challenges Identifying Subjects

- ❑ Number of Studies Being Conducted Has Grown Substantially
- ❑ There are Fewer 'Healthy' People in the U.S.
 - Many Americans are Being Diagnosed Earlier in Life
 - Availability and Variety of Prescription Medications
- ❑ Many Historical Subjects (Students) are More Aware of Risks Associated with Early Research

Most Clinical Trials Do Not Complete on Schedule

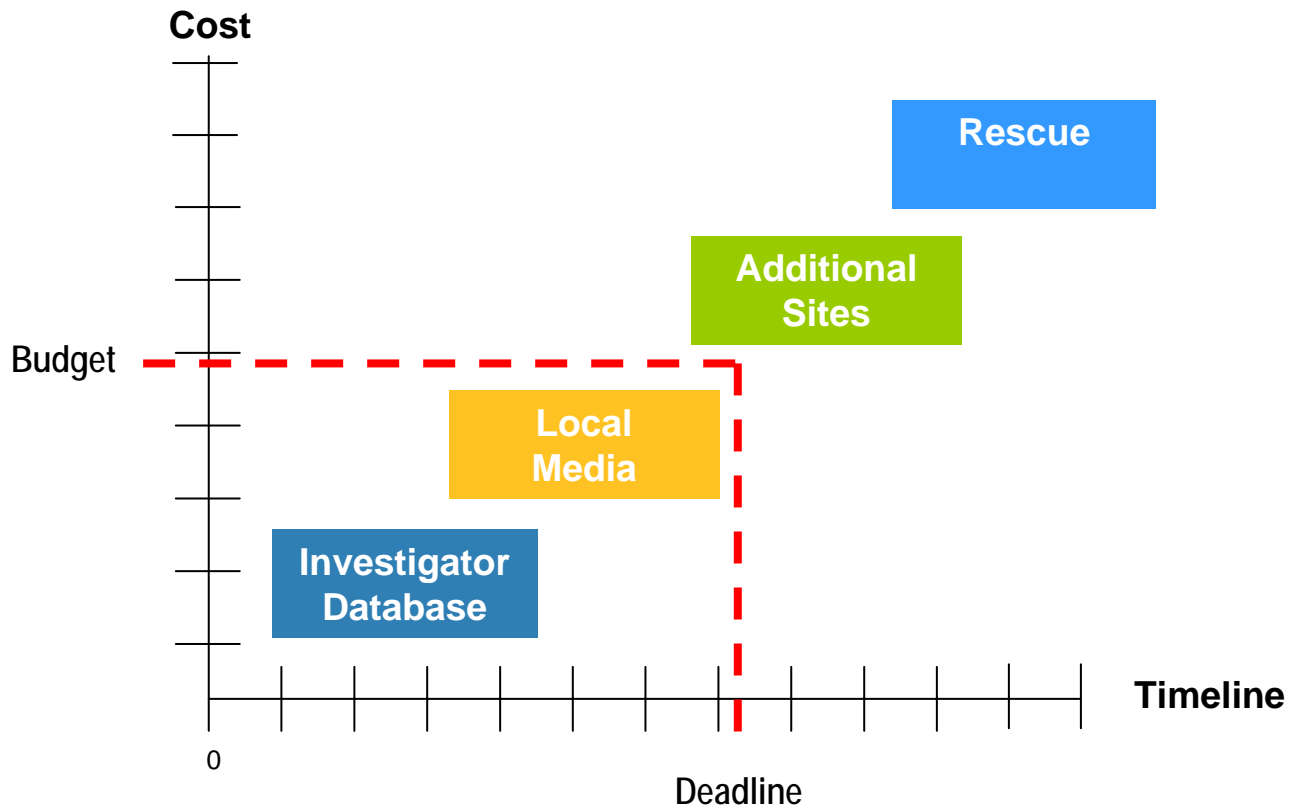
- ❑ Outpatient Studies Typically 5 Months Late
- ❑ Inpatient Studies Typically 9 Months Late



Diversifying Patient Populations Seeking the Ideal Patients

- Outreach to a Wider Audience
- Create Messages Targeting Special Populations
- Use Traditional, Cost-Effective Media
- Variety of Phase I locations

Non-Adaptive Industry Response to Insufficient Patient Enrollment



Resulting in Dramatic Delays and Costs

Successful Patient Recruitment Strategy

- Employ Efficient Outreach
- Target Special Populations with Messaging and Outreach Vehicles
- Retain All Interested Candidates - Even If They Do Not Qualify for the Trial Recruiting
- Capture Comprehensive Medical Histories of Interested Candidates
- Influence Perceptions of Clinical Trials With Ethical Messages

Capabilities of Patient Recruitment Companies

- ❑ Experienced Advertising Agencies
- ❑ Provide Cost-Effective Access to Any Media
- ❑ In-House Creative & Media Production Dedicated Web
 - ❑ Radio
 - ❑ Television
 - ❑ Print Ads
 - ❑ Site Support Materials
- ❑ Regulatory Affairs Group with Vast Experience in Meeting IRB Ethics, Regulatory and HIPAA Guidelines



Comprehensive Site Support Materials Increase Investigator and Patient Awareness and Improve Retention

- ❑ Study Specific Posters
- ❑ Brochures
- ❑ Appointment Reminder Cards
- ❑ Inclusion/Exclusion Cards
- ❑ Patient Directed Letters
- ❑ Physician Directed Letters
- ❑ Informational Web Module
- ❑ Patient Educational Videos



Study Specific Web Sites & Online Registries

Benefits to Patients:

- ❑ Up-to-date Disease and Study Information
- ❑ Opt-In Database Building
- ❑ Internet Searchable
- ❑ Allows Patients Privacy
- ❑ Reduces “Fear” of Live Contact
- ❑ Transferable to Live Call Center personnel

Benefits to Study/Sponsor:

- ❑ Readily Adaptable to Any Protocol
- ❑ Cost-Effective Highly Targeted to Younger and Chronic Disease Populations
- ❑ Robust Metrics Track Hits, Screening Events, Dispositions



Phase I Patient Recruitment Services

Clinical Advertising

- Effectively Target Special Populations & Symptomatic Patients
- Placement of Cost-Effective Media

Central Screening

- Review Subjects Against Multiple Protocols
- Match Subjects for Best-fit
- Ensure Patient's 1st Appointment
- Arrange Transportation & Logistics

Patient Databases

Regulatory Affairs - IRB Review, Regulatory and HIPAA Guidelines

Sometimes Simpler Is Better

Are You:

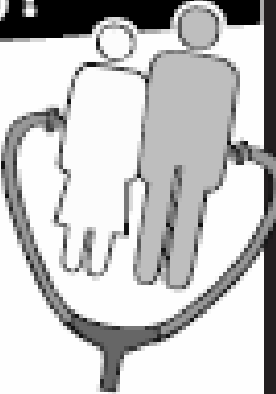
In Good Health? At Least 40?

(Site name _____)
is seeking healthy volunteers
to participate in a cardiac
medical imaging study.
Qualified participants will
receive at no charge:

- Physical Exam
- Laboratory Evaluations
- Electrocardiograms
- 20 Day Follow-Up

Qualified participants will receive \$200
upon completion of the study.

**For More Information,
Call Toll Free 1.866.257.6667**



Creating Phase I Patient Databases

- Reposit All Respondents to Outreach in a Valuable Database for Continued Searching and Use
- Patient Medical Profiles Are Stored in Searchable, Extractable Database Formats
- Database Candidates Save Time and Outreach Costs for Recruitment
- Patients Can Be Matched to the Appropriate Protocol
- Ability to Target Symptomatic Patients

inclinix
Delivering Results