



Innovative Clinical Development Solutions

*PM*TRIALS
QUALITY MOBILE RESEARCH



pcmtrials.com

Putting Patients First: Taking Trials & Technology Home

Medidata NEXT

Background

- Less than 10% of rare diseases have a specific treatment
- Most have no cure and manifest at a young age
- Clinical trials in rare diseases are more challenging than trials in frequent diseases.
 - Small numbers of eligible trial participants
 - complicated by heterogeneity among rare disease patients

Introduction

Individuals and their parents are likely to be exploring clinical trials as part of their treatment journey

- If the burden of participation is considered out of proportion, recruitment may fail or participants may drop out early
- Many individuals have other debilitating conditions/ have physical limitations making it difficult to attend frequent study visits
- Both patients and parents often need to keep a job and manage other varying family activities

A Brief History

- Home visits have been part of clinical research since 2003
- Acceptance slow at first, accelerated in recent years
- Providers growing in number
- Models evolving with technology

Mobile Research Activities

RN Scope Of Practice | Portable Equipment | Acceptable Risk

- Administer product (e.g. infuse, inject, oral, inhaled, topical)
- Draw specimens (e.g. blood, urine, saliva)
- Assess subject (e.g. AEs, concomitant medications)
- Manage wearables
- Educate subjects
- Other – “outside the norm is the new norm”

Technology Integration

Bringing successful clinical trials into the 21st century

- Electronic Clinical Outcome Assessments (eCOA)
- Image collection for central review (i.e., photographs)
- Collection of samples for central laboratory analysis
- EDC entry
- The combination of home study visits and the right technology modules removes barriers to optimal patient recruitment, compliance, and retention

Meeting the Needs of a Diverse Participant Population

Traditional Home Visit Participants:

- Fragile
- Immobile
- Rare/Orphan
- Pediatric or Elderly

More Recent Patient Populations:

- Female
- Diverse Ethnicities
- Employed
- Enrolled in School

Achieve More, Faster

- Complete Data sets are possible
- More accurate feasibility projections
- Accelerated recruitment
- Improved retention rates
- Increased overall compliance
- Practice actual patient-centricity, while remaining cost-neutral
- Knowing how to overcome logistical and regulatory challenges
 - International sites and agencies
 - Registry recruitment
 - Virtual or hybrid trials

Our Special Teams Solve Unique Challenges

Some examples of our past experiences:

- Alzheimer's Cognitive Function Testing
 - **Challenge:** Sponsor/CRO wanted to conduct remote trials by testing cognitive function of participants with Alzheimer's. Sponsor was concerned with variability of many different agencies and nurses.
 - **Solution:** Chose PCM TRIALS due to employed-nurse model which also utilized special teams when needed. Eight nurses, which were licensed in all 50 states, were specifically trained on the cognitive test which limited the sponsor's variability concern.

Best Time to Consult?

- During feasibility with your CRO
- Advisory board and patient affinity meetings
- During the bidding process
- When rescue is needed
- Anytime you have a question!

Contacts



ELLEN WEISS

VICE PRESIDENT, BUSINESS DEVELOPMENT

303.253.717

Ellen.Weiss@PCMTRIALS.com



HEATHER PADEN

HEAD OF CLINICAL OPERATIONS

617.335.9145

hpaden@prometrika.com

