Advancing Patient-Centered Mobile Clinical Trials by Implementing At-home Study Visits

CTTI Legal & Regulatory Issues Affecting the Adoption of Mobile Clinical Trials
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Agenda

• Patient-centric at-home study visit model

• Case Studies

• Win-win benefits to stakeholders
What does patient-centricity really mean?

Making the study subject a central consideration in the design and implementation of a clinical trial; allowing subjects to participate in a study and carry on with the least disruption to their normal daily routines.

An innovative patient-centric approach to patient recruitment and retention may prove to be an important solution for many studies: mobile clinical trials using an ambulant care service model to take selected study visits to the patient.
By conducting selected protocol visits at home, workplace or other alternate location, ambulant healthcare providers offer a way for patients to participate in trials regardless of:

- Study duration
- Frequency of visits
- Disease state
- Distance to site
- Vacation/travel
- Family, school, work or community obligations

Making trials more convenience and comfortable for patients will result in more patients willing and able to participate and remain in the study
Centrally Managed Ambulant Care Mobile Service Model

- First established in 1992
- Utilized by hundreds of pharmaceutical, biotechnology, and medical device companies (including single product companies to the top 10 global pharmaceutical manufacturers)
- Generally contracted by sponsor and services made available and to all sites (complimentary) and patients (optional) to use as desired
- Used to support over several hundred studies in a variety of therapeutic areas
- Incorporated in numerous NDA programs for NMEs which have subsequently received commercial approval including several blockbuster products
Mobile Services Available

Services:
- Study drug administration (infusion, injection, topical)
- Blood draws (safety labs, pharmacokinetics, genomics) and other biologic sampling
- Clinical assessments (vital signs, ECGs, concomitant medications, adverse events)
- Patient training and education (e.g., self-administration)
- Study compliance checks (patient diary, drug storage), patient questionnaires
- Study coordination at investigator sites

Age Groups:
- Pediatrics, adolescents, adults, geriatrics

Modes of Therapy Administration:
- Intranasal
- Intravenous
- Oral
- Topical
- Subcutaneous infusion
- Subcutaneous injection

Phase 1 to Post-Marketing Studies
A centrally managed ambulant care network may consist of:

- Regional (domestic) or global service territory
- Pre-qualified healthcare service providers/agencies ranging from 100’s to 1,000’s of providers or agencies. Service providers may consist of nurses, doctors, and/or other professionals (e.g., NP, PA, phlebotomists)
- Owned/employed, franchised, or sub-contacted relationships
- Management teams may be local, regional, and/or global
Centralized Managed Ambulant Care Service Provider—Global Model

Global Corporate Functions (Management, Sales & Marketing, HR, Legal, Policies & Procedures)

Regional Operations (Project Managers)
- North America
- Europe
- Latin America
- Asia-Pacific

Country Operations (Country Coordinators)
- North America
  - USA
- Europe
  - Germany
  - UK
- Latin America
  - Brazil
  - Chile
- Asia-Pacific
  - Korea
  - Australia

Local Services (Service Providers)
- North America
  - USA
- Europe
  - Germany
  - UK
- Latin America
  - Brazil
  - Chile
- Asia-Pacific
  - Korea
  - Australia

Flexibility to quickly and cost effectively increase or decrease network size
CASE STUDY:
- Phase II US Study
- Glioblastoma
- 1-hr infusions, 3x/wk for 6 mos
- Plan: 50 subjects within 12 mos
- 6 mos: recruitment behind schedule

RESULTS:
In-home nursing and pharmacy in place within 3 weeks:
- Enrollment rate more than tripled
- 7 of 10 sites recruited out of state subjects

CASE STUDY:
- 4 Phase II/III studies in the US
- Rare pulmonary disease
- Oral daily dosing for up to 2 years
- Lab visits for blood draws (weekly or more frequently)
- Subjects often missed lab visits

RESULTS:
Ambulant care blood draws started 1 year into study for 69% of subjects, followed by dramatic improvements in:
- Over 500 patients enrolled
- Blood draw compliance
- Subject retention

CASE STUDY:
- Phase 1 study
- Relapsed/refractory CD30-positive hematology malignancies
- IP administration, weekly x3, 28-day cycles, 2-hr IV infusions
- 140+ sample time points/subject
- Subjects often missed lab visits
- PK/PD, immunogenicity and safety labs
- Limited patient population

RESULTS:
Ambulant care services provide high retention and robust data:
- 46 patients enrolled, none withdrew consent
- Approximately 460 visits were conducted at home and over 1,000 blood samples were collected
- Approximately 60 visits were performed over weekends throughout the study
- PK/PD analyses were robust, supported by strong data
- Study end point met
CASE STUDY:
• Phase III study
• Multi-center, North America and Europe
• Rare disease (Alpha-1 antitrypsin deficiency)
• Randomized, double-blind, cross-over study (16 wk double blind, 8 wk open label)
• IP administration, weekly 1-hr IV infusions (+/-1day); serial pK samples and safety labs
• Limited patient population

RESULTS:
Ambulant care services provide rapid enrollment and high compliance:
• Study start delayed by several months, but completed enrollment ahead of schedule—**all patients (n=59) enrolled within 3 months**
• Services available weekends and evenings
• Services available for emergent/out of scope needs (retests, traveling patients)
Homecare services accelerated enrollment completion by 8 months. 80% of patients (n=47) used homecare services.
“It would be very difficult to conduct serial blood draws by regular site staff and the assistance of home nurses has been very valuable” (Study Site)

“Subject did not want to stay a whole day at the hospital. Instead, she was sunbathing at her garden” (home nurse)

“Subject would have to drop-out of the study, when he disease progressed and he was no longer able to self-inject the drug. He is located 500 Km away from the site.” (Study Site)

“We have a subject living in Northern Ireland and our site is located in London. Home visits are key to keep the subject in the study. Most of our patients chose to be visited at their homes, even when located not so far” (Study Site)

"With my restrictions, my husband would have to miss days off work to take me to my hospital appointments. It would be all so much more difficult." (patient)

"With your availability and your work, I'm hopeful that I can have a better quality of life." (patient)

"In my opinion, home care services are of major importance in the context of clinical trials, since they contribute to minimize study travels burden, reinforce protocol compliance and most of all, to an effective increase in patients quality of life.” (study site)
Collaboration on patient-centric services resulted in winning solution for all parties:

- **Patients/Parents** appreciate the convenience, flexibility and comfort of ambulant care services
- **Investigators** - able to recruit and retain patients from a broader geographic area, better compliance
- **Sponsor** - realization of shorter development timelines
- **Goal for Consumers** - get access to new therapies sooner
Thank you for your attention!

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