Patient-Centric Services in Clinical Trials

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Agenda

- Market drivers that support patient-centric solutions
- Traditional direct-to-patient distribution practices - benefits and challenges
- Solutions incorporating ambulant healthcare services
- Patient-centric ambulant care at-home study visit model
- Case studies using at-home healthcare services to improve patient recruitment, compliance and retention
- Q&A
Drivers for Patient-Centric Studies

- Soaring costs of conducting clinical trials
- Rising cost per clinical trial patient
- Study delays due to patient recruitment
- Study integrity concerns due to patient non-compliance or high drop out rates
Patient-Centricity

What does patient-centric really mean?

Definition:
Making the subject living with the disease a central consideration in the design and implementation of a study; allowing subjects to participate in a study and carry on with the least disruption to their daily routines
Patient-Centric Initiatives

- Patient communication and engagement initiatives
- Clinical research awareness programs
- Patient and trial databases and matching tools
- Social media and technology platforms
- Direct-to-patient courier services
- In-home visits conducted by ambulant healthcare providers
Patient Attitudes and Perceptions

• Patients want to comply with clinical trial instructions and they want studies to succeed
• Customization and accommodation of individual differences is essential
• There is a clear need for improving the study product return process

2013 ISPE Report of Patient Experiences with Clinical Trial Material
78% of patients indicated that it would be either “very helpful” or “somewhat helpful” to have their repeat prescriptions delivered to their homes.
Direct-to-Patient Services

• Delivery of clinical trial materials from an investigator site, pharmacy or depot directly to the patient’s home by a specialty courier

• Home pick up and delivery of unused / partially used / expired clinical trial materials for return to site or depot

• Provided regardless of where patient is located

• Provided at a time convenient for the patient
Benefits/Challenges of Direct-to-Patient Services

Benefits:
• Decrease patient travel to the site
• Increase patient convenience
• Ensure door-to-door cold chain logistics

Challenges:
• Cannot enter patient’s home
• Only for drugs being self-administered
• Cannot observe proper storage in home
• Cannot administer drug to patient
• Cannot address immediate clinical issues with patient
In-home Visit by Ambulatory Healthcare Providers

- Ability to enter patient’s home and conduct study drug compliance checks (proper storage, expired study drug, inventory)
- Provide supervision/corrective training of self-administration in the home
- Provide administration of study drug by trained clinicians
- Conduct other protocol visit requirements
Business Model Concept

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
• 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
In-Home Ambulant Care Services

- Blood draws for local/central laboratory processing (including safety labs, pK, specialty labs)
- Other biological sample collections (e.g., urine, pharyngeal swab)
- Study drug pick-up and delivery
- Study drug administration
- Patient training and education
- Device management (infusion pump)
- Provision of ancillary supplies/concomitant meds
- Clinical assessments and questionnaires
- Local and central pharmacy services
- Source documentation/communication
Ambulant Care Service Provider Networks

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 1000’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
- Local, regional and/or global management teams for:
  - coordination and training
  - standardization
  - compliance
Centrally Managed Global Network

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

Global Office(s)

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

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

Local Services (Service Providers)
- USA
- Canada
- Germany
- UK
- Brazil
- Chile
- India
- Australia
Ambulant Care Service Experience

- First established in 1992 for clinical trials
- 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 350 studies in a variety of therapeutic areas
- Incorporated in numerous NDA programs for NMEs which have subsequently received commercial approval including several block buster products
Ambulant Care Services - Global Model

SPONSOR

INVESTIGATOR SITE

COUNTRY COORDINATOR

CENTRAL MANAGEMENT TEAM

LOCAL SERVICE PROVIDER

STUDY PATIENT
Ambulant Care Provider Responsibilities

• Develop study-specific ambulant care training manuals and documents
• Train Country Coordinators on study-specific requirements
• Receive physician orders for study-specific services (within country) – 1 order per patient
• Qualify and train local Service Providers on study requirements
• Coordinate and oversee in-home or alternate location study visits
• Provide timely documentation of visits to the investigator sites
• Communications with sponsor, investigator sites, central labs and local ambulant care service providers
• Centralized billing (monthly)
• Quality assurance, regulatory compliance, records retention
• 24/7 availability, 365 days per year
Case Study #1 – Recruitment Rescue

**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 wks:
- Enrollment rate more than tripled
- 7 of 10 sites recruited out of State subjects

Case Study #2 – Retention Rescue

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 #3 – Proactive Compliance

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 1000 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 #4 – Proactive Recruitment

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 11 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)
Case Study #4 (cont.)

Homecare services accelerated enrollment completion by 8 months. 80% of patients (n=47) used homecare services.
Summary of Benefits

• Long-term studies or studies requiring frequent site visits

• Patient is unable/unwilling to travel to site for protocol-related activities due to:
  - disease state
  - distance/geography
  - travel/vacation
  - transportation
  - inconvenience
  - age (pediatric or elderly)
  - school, work, family responsibilities

• Available for all age groups (peds – geriatrics)

• All phases of development
Summary (cont.)

Ambulant care services can create benefits for all stakeholders:

• Faster recruitment, better compliance, higher retention rates
• Increased patient convenience and comfort
• Increased Investigator site satisfaction and compliance
• Shortened development time
• Provide quicker access to life enhancing products for patients and their families
Patient Centric Service in Clinical Trials

Thank you for your attention!

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