Patient recruitment and retention challenges

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Disclosure

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I have the following potential conflicts of interest to report:

☑️ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Clinical Trials: Patient recruitment and retention

- The challenge
- Planning Recruitment & Retention
- Patient centeredness
- Technology to engage patients
The challenge
Patient recruitment and retention

- The demand for patients is growing exponentially
- The number of investigation sites is growing linearly
- 80% of studies are delayed by 1/3 or more of their intended durations\(^1\)
- Up to 30% avg. drop-out rate across clinical trials\(^2\)

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1 KB Drennan, Patient recruitment: the costly and growing bottleneck in drug development. Drug discovery today, 7(3) 167-170 (2002)
The challenge
Patient recruitment and retention
Effects of Poor Recruitment and Retention

- Decline in motivation for staff and subjects
- Increased costs
- Reduced statistical power
- Reduced internal and external validity
- Loss of position and/or revenue for the product

J Sullivan. Subject Recruitment and Retention: Barriers to Success; Applied Clinical Trials, Apr 01, 2004; www.appliedclinicaltrialsonline.com
Plan Your Success
Planning considerations

- Never assume that investigation sites will be able to find all their study patients without assistance
- Get actual patient perspectives before building a recruitment plan
- Try to understand feelings and emotional drivers of patients
Planning considerations

- Is the target disease well-known?
  - Data about incidence and prevalence of the disease
- Are patient advocacy groups active?
  - How can we engage them?
- If not, what could be appropriate alternatives?
  - Study forum platform
  - Health information websites
Planning considerations

- What is a realistic recruitment period?
  - Less than 1 year, ≤ 5 years, longer?
- How can the recruitment period be reduced?
  - Increased number of study sites
  - Pro-active recruitment strategies
  - Ask KOL’s for appropriate PI’s
- What is the most cost-effective solution?
What is Patient Centeredness?

- Health care that establishes a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients' wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care.¹

- Patients as key stakeholders in all aspects of trial design and execution

When is Patient Centric Design Especially Useful?

- Rare disease
- Restricted access to study sites
  - Patients with mobility issues
  - Rural area
  - Limited number of study sites and/or competence centers
- Collection of data from multiple sources
Factors for Patient Centric Trial Design

Market Research

- Demography (gender, age, education)
- Geography (urban vs. rural)
- Psychology (attitude/life-style)
- Behavior of patients
- Disease impact on the patients’ quality of life
- Satisfaction with current treatment options
- Preferred ways of communication / information exchange
- Perceptions and attitudes about specific study procedures
- Participant’s expectations
Factors for Patient Centric Trial Design

Market Research

- Acceptability of trial design
  - Feasibility of defined selection criteria
  - Patient relevant outcome measures
  - Frequency and duration of site visits
- How to minimize trial design related burdens
- To create awareness about the trial and the device
Factors for Patient Centric Trial Design

Informed Consent

- Use simple and clear language
- Keep information documents short and precise
- Set realistic expectations upfront
  - Benefits
  - Time and effort for the patient
  - Study objectives and endpoints
- Address concerns regarding the participation in the trial
- Enable trial candidates to make truly informed decisions
Factors for Patient Centric Trial Design

Patient Friendly Environment

- Offer flexible visit schedules:
  - Consider caregiver schedules if relevant
  - Offer accommodation options
- Improve the interaction between the patients and the investigational sites
- Create a friendly atmosphere at investigational sites
  - Limit or eliminate barriers
  - Be sensitive to patient’s comfort and needs
Factors for Patient Centric Trial Design

Participants as Important Stakeholders

- Establish long term relationship
  - Patient <-> Site staff <-> Sponsor
- Communication at eye level
- Promptly respond to inquiries
- Use preferred communication formats
  - Print, SMS, Email
- Frequency and content of updates
  - Trial progression
  - Overall results
    - (73% of participants wish to get a summary of the study results*)
  - Individual results
  - Present results in a way easy to understand for participants
  - Data transparency to build trust
- The patient’s feedback is important

* https://www.ciscrp.org/download/2015-perceptions-insights-study-participant-experiences/?wpdmdl=5742
Factors for Patient Centric Trial Design

Retention Support

- Reminders of upcoming visits
- Calls between visits
- Share of new information
- Study hotline / Study forum platform
- Show appreciation and recognition

• Avoid terms such as „subject“
Factors for Patient Centric Trial Design

When do I need retention strategies?

- The planned study participation is longer than 6 months
- Intervals longer than 1 month between two consecutive visits
- Constant motivation is required by the patient
- The patient is required to perform some tests at home
Factors for Patient Centric Trial Design

What do Trial Participants Like?

- Helping advance science and the treatment of my disease/condition: 35%
- Helping others who may suffer from my disease/condition: 28%
- The compensation (money) I received: 25%
- The amount of care and attention that I received from the study doctors and staff: 21%
- The information that I learned about my disease/condition: 18%
- My relationship with the study staff: 17%
- The positive response that I had to the study drug/intervention: 16%
- The free medical procedures and care that I received: 15%
- The free study drug that I received: 14%

https://www.ciscrp.org/download/2015-perceptions-insights-study-participant-experiences/?wpdmdl=5742

PATIENT CENTEREDNESS
Factors for Patient Centric Trial Design

Reasons for Drop-out

- I was mostly motivated by myself to stay in the study
- The site visits were stressful
- I am satisfied that my questions were answered during the IC discussion
- It was difficult to understand the ICF

Technology to Engage Patients
Important to consider

- Selection of the best technology to communicate with the patient
  - Are the chosen tools the best option for the target population?
  - Are the chosen tools manageable by sponsor and investigators?
Summary

- Get to know your patients and establish long term relationships
- Involve patients early in trial design
  - Selection criteria
  - Meaningful outcomes
- Offer appropriate (technological) solutions
- Enable truly informed decisions
  - Data transparency and intuitive presentation of results
- Offer flexibility
- Acknowledge the patient’s contribution
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