A Guide to Implementing Patient Recruitment Strategies in Clinical Research

Speaker: Dr Gillian Lakareber – ICR
1 May 2019
Contents:

• Objectives
• Introduction
• Factors influencing Patient Recruitment
• Recommendations
• Site specific Recruitment Plan
• Conclusion
• Acknowledgements
Objectives

The objectives of this presentation are:

• Create awareness of the importance of successful patient recruitment in clinical research

• Explore the techniques employed to increase patient recruitment

• Provide guidance on the process of implementing a successful patient recruitment plan for a clinical study

• Explore the challenges encountered during patient recruitment and ways to mitigate them
Introduction

• A key problematic hurdle for clinical researchers in the current environment is the ability to enrol the optimal number of patients onto clinical trials.

• Slower recruitment can lead to significant financial losses and delay in getting life saving interventions to patients. As a result, many studies fail to meet their recruitment targets (McDonald et al., 2006).

• Continuous pressure on clinical study teams can lead to stressful and ineffective working environments.
Factors Affecting Patient Recruitment

Source: Lakareber, G. (2016). Factors Influencing Patient Recruitment In Clinical Research: A Qualitative Analysis. California Intercontinental University,

- Researcher Characteristics
- Participant Characteristics
- Systems & Procedures
- Nature of Research
- Technology
- Location

Challenges:
- Lack of early planning
- Lack of awareness about patient recruitment strategies
- Possibility of slow recruitment based on target population.
- Differentiating the study versus the competition.
Recommendations

✓ Leverage new technologies to assist with data sharing and patient engagement

✓ Use real-world data integration and data extraction techniques to assess feasibility

✓ Use short health awareness videos to highlight the benefits of clinical trials

✓ Increase the use of online social platforms like Facebook, Twitter, and YouTube

✓ Create online forum for participants to share experiences

✓ Create shared research databases which contain target population

✓ Advertisements in magazines, newspapers, and radio

✓ Using pre-screening websites

✓ Using online forums to identify potential participants

✓ Using databases to assess eligibility
Participant Characteristics

Recommendations

✓ Retention – engage with patients and ensure they continue their study participation throughout their study journey.
✓ Leverage the active advocacy organizations and patient groups in the region via outreach and social media to raise awareness about the study and direct potential referrals to study sites.
✓ Develop strong partnerships with study sites to foster a shared goal of recruitment and retention success, thereby supporting the progress of the study.
✓ Provide ethically approved incentives like thank you cards, diaries, travel bags, and pens
✓ Establish clinics/support groups or social events to disseminate trial information
✓ Increase publicity of positive patient experiences
✓ Use mobile apps which allow patients to access trial information like visit guides.
✓ Include patients in protocol planning and design
✓ Empower patients to ask about clinical research activities
✓ Increase financial support for patients
✓ Increase the use of interpreters and support for non-English speakers
Recruiter Characteristics

RECOMMENDATIONS

✓ The Principal Investigator should invest more time in patient identification
✓ Offer patients with clear explanation of the benefits and risks of the trial
✓ Offer patient recruitment training to inexperienced members
✓ Recruiters increasing their flexibility during patient recruitment
✓ Site initiation visit and investigator meeting training
✓ Research nurses are available to discuss study during clinic appointment
✓ Research is usually initiated by patient’s doctor
✓ Recruit a dedicated study coordinator or research nurse
## Recommendations

- Evaluate feasibility before study initiation
- Pre-screen clinic notes to identify potentially eligible patients
- Detect patient identification centers near hospitals
- Seek additional funding from government organizations
- Implement a robust feasibility and site selection process
- Share trial results with patients
- Conduct research to ascertain the materials and resources required to help recruiters succeed in patient recruitment
- Pharmaceutical industry should promote patient engagement, be more transparent and socially responsible
- Start a patient recruitment team who primarily identify patients. Provide incentives to research teams with successful recruitment
- Increased collaboration with primary care clinicians
- Focus on building and maintaining strong rapport with recruiters and patients
- Alleviate pressure on recruiters’ workload by increasing resources and funding
## Location

<table>
<thead>
<tr>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Strategically place clinical sites near patients in order to decrease participant burden</td>
</tr>
<tr>
<td>✓ Collaborate with local services to overcome logistical issues</td>
</tr>
<tr>
<td>✓ Offer expense reimbursement for travel</td>
</tr>
</tbody>
</table>

## Nature of Research

<table>
<thead>
<tr>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Protocol amendment to increase acceptability</td>
</tr>
<tr>
<td>✓ Have the right patient cohort</td>
</tr>
<tr>
<td>✓ The design of the study and protocol needs to be conducted in a risk and data aware manner</td>
</tr>
<tr>
<td>✓ Flexible recruitment schedule for patients and decreasing the time commitment on patients</td>
</tr>
<tr>
<td>✓ Make the inclusion/exclusion more realistic</td>
</tr>
<tr>
<td>✓ Implement study visit run-throughs in which potential participants are given a deeper understanding of study expectations</td>
</tr>
</tbody>
</table>
Guide to developing a Site Specific Recruitment Plan (SSRP)

The SSRP is a data collection tool used to facilitate engagement of study teams by identifying and implementing successful strategies for patient recruitment based on study specific requirements.

Conduct a SWOT analysis (strengths, weaknesses, opportunities, threats):

✓ What are the main challenges/weaknesses/threats?
✓ What are the main strengths?
✓ What strategies can we employ based on the opportunities?
✓ Accountability and implementation - How can we implement these strategies?
✓ What is the contingency plan?

Table 1: Forecasted subject recruitment (Goal is to enroll 1 - 2 patients in 12 months)

<table>
<thead>
<tr>
<th>Date of forecast (dd mm yyyy)</th>
<th>No. of subjects expected for randomization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimation of Site Evaluation Visit (IV):</td>
<td>8 Jan 2018</td>
</tr>
<tr>
<td>Estimation of Site Initiation Visit (IV):</td>
<td>6 Mar 2018</td>
</tr>
<tr>
<td>Current Estimation:</td>
<td>6</td>
</tr>
<tr>
<td>First Subject In (FSI) target date for site:</td>
<td>30 Mar 2010</td>
</tr>
<tr>
<td>Comment If there are differences:</td>
<td>No differences</td>
</tr>
</tbody>
</table>
Conclusion

• To accelerate new interventions, a **collaborative approach** should be adopted. We need to think about patient recruitment earlier on in the research process.

• **Patient centricity** and factors which affect participation should be the focus of clinical researchers in order to alleviate the challenges we are facing.

• **Effective communication** among study teams by sharing success stories from high enrolling sites and good working practices is required.

• **Increasing site engagement** to address study challenges, by ensuring **adequate training** has been provided on study procedures and the inclusion/exclusion criteria.

• Adopting a **multi-faceted approach through outreach initiatives and recruitments tools** will inform, educate and communicate with patients about the study will encourage participation in clinical trials.
Acknowledgments:

- Patient Funnel Analysis – Adopted from Clinical Performance Partners, Inc


Thank you