

The Patient Recruitment Challenges Can Emerging Regions Help?

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Recruitment of Volunteers...

- Most under-estimated and most crucial part of a human clinical study
- Not planned early enough
 - “All eggs in one basket” syndrome
 - Trouble-shooting versus Trouble-Prevention
 - One size fit all strategies
- Poorly planned
 - Recruitment strategies
 - Expanding exposure

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Challenges to Recruitment

- Lack of patient pools
- Availability of competing treatments
- Standard of care available
- Quality of life of patients
- Length and frequency of treatment
- Public relations and public awareness

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Recruitment is Getting Harder

- Too many trials
- Few experienced sites and investigators
- Good standard of care (in US and Western EU)
- Few truly innovative therapies (wonder drugs)
- Many high profile failures

Recruitment strategies are critical

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Emerging Regions of the World

Formerly known as the “Third World”

- BRIC: Brazil, Russia, India and China
- South-East Asia: Korea, Malaysia, etc.
- Other countries in South America
- Eastern Europe: Poland, Romania, Ukraine, Serbia
- Africa (only for a few indications)

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Emerging Regions are Pooled for a Reason

- Similar health-care infrastructure
- Similar patient pools
- Similar economic conditions
- Similar history of clinical trials
- Similar political and business environments
- Similar access to resources

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Role of Emerging Regions in Meeting Recruitment Goals

- Few trials
- Few investigators and sites (but rapidly increasing)
- Relatively limited availability of Western standard of care
- Large treatment-naïve patient pools

Role of Emerging Regions in Meeting Recruitment Goals

Additional advantages:

- High rate of patient compliance
- Patients in dire need for standard treatments
- “Few” regulatory hurdles (case-by-case)
- Business friendly environment
- Future markets

Common History

- Most clinical trials were Government funded and supported
 - Since at least 25 years
 - Mostly at govt. hospitals
 - Mostly on collaborative projects with other governments
 - Few Regulations
- Private-funded research mostly started in the last 10 years, at most.
 - Mostly multi-national corporations
 - Mostly large multi-national CROs
 - Indigenous CROs with limited experience

Perceptions

- Reduced Cost
 - Per patient cost
 - Data management
 - Trial management
- Reduced Time
 - Rapid recruitment
 - All indications
- Friendly Regulatory Environment
 - Easier approval
 - Faster than US/EU
 - Less restrictive than US/EU

Huge Untapped Potential

- Technical
 - Physicians and hospitals/clinics
 - Ph.D.s, pharmacists, nurses, etc
 - Training resources
- Resources
 - People
- Financial
 - For larger trials
 - Rapid recruitment
- Language & Culture
 - Language is an issue in most regions
 - Huge US influence

Definite Need for a Recruitment Strategy

- Based on indication and population
- Time of initiation of trial
- Plan for regulatory, ethics, GCP and quality issues
- Components of strategy
 - No and location of sites
 - Personnel requirements
 - Advertisements and promotions
 - Measures to ensure non-coercive activities

Recruitment Plan

- **Who** is going to recruit, and who are you looking for?
- **What** is your message?
- **What** are your barriers?
- **When** to initiate recruiting?
- **Where** do you recruit?
- **How** do you recruit?
- Evaluate your recruitment efforts

Framework for Message

- Be honest
 - What you are doing is research
 - It is experimental or investigational
 - There are unknowns
 - There may be risks
 - There may or may not be benefits
- Be clear
- Be creative and engaging
- Clarify scientific jargon
- Make analogies
- Assure confidentiality
- Answer questions

Training and Quality Management

- Written plans with version control
- Collection of feed-back and documentation of changes
- Setting goals and time-lines
- Getting regulatory, ethical and financial approvals before implementing
- Adaptive recruitment

Training and Quality Issues

- General Issues
 - GCP Compliance
 - Ethics: Approvals by valid of IRB/IECs
 - Approval from regulatory agencies
 - SOPs and Training Issues
 - Documentation
- Compliance issues
 - Coercive actions
 - Unapproved processes
 - Undocumented processes

Customized Recruitment Strategies

One of the most important component!

- Build a comprehensive recruitment plan
 - Site qualification
 - Investigator qualification
 - Advertisement and promotion of trial
 - Recruitment camps
 - Incentives: Site personnel and patients
 - Within reason and approved by IRB/IEC
- Get plans approved by all applicable IRB/IEC
- Execution of plan
 - Training, initiation, communication and follow-up
 - Trouble-shooting

Role of Public Relations

All our knowledge is the offspring of our perceptions – Leonardo Da Vinci

- Role of media in emerging regions
 - Very vocal, less knowledgeable
 - Short attention span
 - Long-term influence
- Public perception of foreign sponsor
 - Deep pockets
 - Extended reach
 - Higher demands for quality and compliance

Future Prospects

- Strong competition among different countries
- Increased use of English as primary professional language
- Higher patient awareness
- Increased cost
- Increased feasibility
- Increased supervision by local regulators and the FDA

Thank You! **Questions and Comments**

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