



e-Patient Recruitment in Emerging Markets

Abstract / Business Case

Patient recruitment costs around 6-7% of the total and it is higher than all other cost components. Almost 80% of clinical trials are delayed due to patient recruitment challenges. This delay adds on to the cost of maintaining staff and site, and shortening the patent period. These issues are pushing clinical trials towards two major shifts – shift from patient recruitment to patient engagement, and shift from site-centric trials to patient-centric trials. Both these shifts require some fundamental changes in the way clinical trials are performed and patient recruitment through electronic medium is expected to be one of those changes. This article will focus on changing recruitment trends within emerging markets and how these markets are bracing themselves for such inevitable changes.

Introduction

Global use of digital and social media in clinical trials gathered momentum after 2010. North America and Western Europe provide comparatively conducive environments for the growth of e-recruitment, whereas in emerging markets, the regulatory and cultural issues limit the use of e-recruitment. Among them Latin America is potentially a good clinical trial market to utilise e-recruitment methods.

Traditional methods		
<ul style="list-style-type: none"> ■ Investigator referrals ■ Print media – newspapers, outdoor posters, brochures, flyers ■ Radio & TV ■ Call centres ■ Local Community outreach/site ambassador ■ Articles in scientific journals 		
Emerging methods (e-recruitment)		
Digital Platforms	Social Media	Mobile Technology
<ul style="list-style-type: none"> ■ Online advertising – Google ads, pop-up advertisements ■ Patient advocacy groups ■ PRO/CRO databases ■ Online patient communities (PatientsLikeMe® and Ben's Friends) ■ Online ambassadors ■ Online clinical trial registries (clinicaltrials.gov) ■ Direct mail 	<ul style="list-style-type: none"> ■ Facebook ■ Twitter ■ Youtube ■ Blogs 	<ul style="list-style-type: none"> ■ Mobile apps – Foursquare, Instagram ■ Text messaging

Source: Secondary research & Beroe analysis

The table above portrays both traditional and e-recruitment methods for patient recruitment. The usage of the type of methods varies between developed and emerging markets. For example, due to regulatory concerns, emerging markets use PRO/CRO databases rather than ads, whereas in developed markets such as North America and Western Europe, search engines are preferred. Taking into consideration the emerging

e-recruitment methods, digital platforms of patient advocacy groups and patient databases contribute more than 70% of usage in emerging markets, whereas social media platforms are more preferred in developed markets.

e-Recruitment of patients is an outcome of loopholes in traditional methods. Issues like delays in patient recruitment, higher cost, less penetration towards rare disease patients, etc. have pushed the market to adopt new methods. Some other issues are mentioned as follows:

Issues for investigator referral:

- Lack of information about clinical trial
- Investigators do not have enough time to educate patients about the trial

Issues for print media:

- Difficult to target required subjects
- Uneducated patients cannot understand
- Response time by the sponsor is more
- Location is the major barrier
- Push strategy

Market Drivers for e-Recruitment

Therapeutic Area - Personalised Medicines, Rare Disease
With growing rare disease therapeutic pipelines, recruitment of patients is growing difficult owing to geographically dispersed patient pool. e-Recruitment offers targeted patient identification and screening according to the protocol requirements. This aids in better screen-to-recruitment ratios, especially in rare disease trials.

However, one must note that not all e-recruitment strategies are equally effective for all therapeutic areas. For example, patient forums and EHRs are very effective in recruitment of patients in rare disease trials; whereas, social media-based recruitment strategies work well for cancer clinical trials.

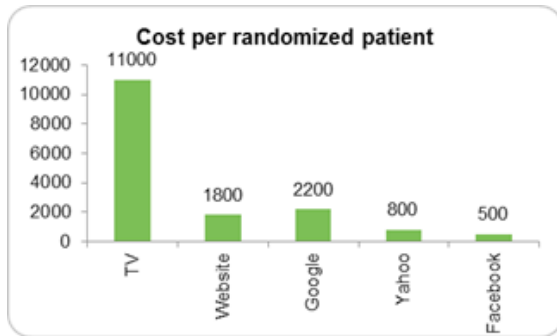
	# OF ADS SHOWN	WEBSITE VISITORS	COST	COST PER VISITOR
Search Engine	10,000 SEARCHES	200	\$997.00	\$4.98
Radio	100,000 LISTENERS	20	\$3,500.00	\$175.00
Print	100,000 READERS	15	\$3,000.00	\$200.00
Direct mail	2,000 PIECES	10	\$4,000.00	\$400.00

Source: <http://www.patientrecruitmentonline.com/>

Cost Advantage

e-Recruitment provides a cost advantage of 70-80 % over traditional methods of recruitment.

So as per industry analysis, the cost advantage for e-Recruitment will be huge followed by higher penetration into the patient base.



Source: WCCT Global Webinar

Facebook is the widely-accepted social network media and also the most economical. So, the pharma companies and CROs are shifting gradually from broadcasting media to social media.

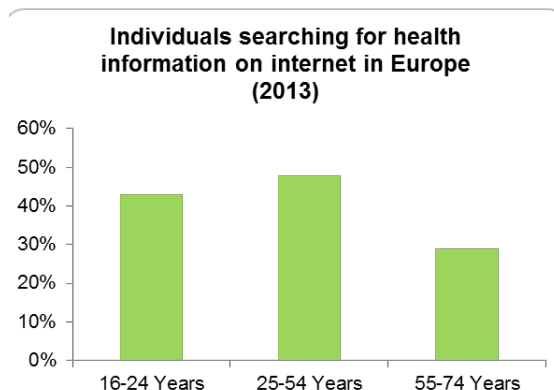
In developed markets, CROs use Facebook as the initial information method in a recruitment strategy mix in order to build the database of right patients that are later targeted using direct mail and call centres. This saves huge cost for the pharma companies.

Timelines

One big issue with clinical trial planners is the unexpected delays in clinical trials due to delays in patient recruitment or patient dropout. One can pre-screen potential participants online so it can speed up the overall trial recruitment process. This can also assist in enhancing the patient time period for trials.

Demographic Advantage

- In developed markets like the US and Japan there is an increase in the population of over-60s.
- Emerging markets like Asia Pacific, Eastern Europe and the Middle East are seeing an increase in the young population.



Source: <http://digital-agenda-data.eu/>
 Statistics reveal that the population belonging to the 25-

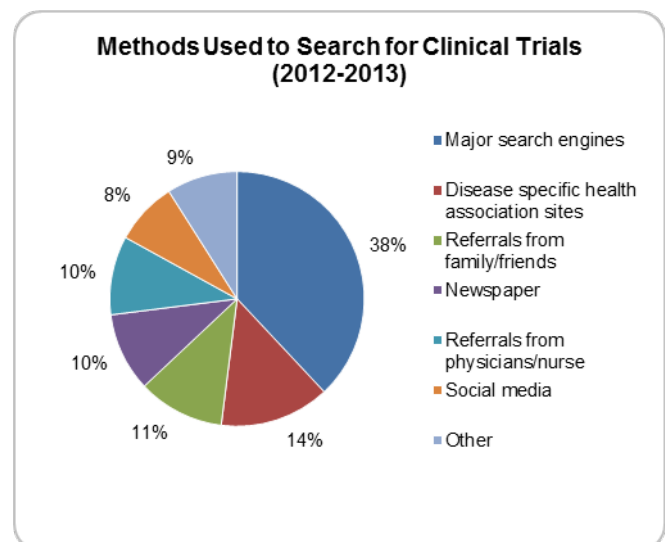
54 years age group have more tendency to use electronic media for health information. This presents a viable opportunity to target this segment of the population through e-recruitment strategies, especially in emerging markets.

Other benefits include the following:

- Help patients in finding a suitable trial in real time
- Location is not a barrier
- Right patients at right time can be targeted
- Pull strategy - studies reveal that altruism is the major clinical trial participation motivator. Use of e-technology will put patients' willingness in the first place
- A good platform to raise awareness and share in detail the prospective outcomes and adverse effects of the study
- Best way to raise awareness and share adverse effects of the study
- In many developing markets like Israel, the government is providing a supportive regulatory environment for CROs to conduct clinical trials to make quality drugs available to the country's population. This is increasing the use of digital media in China, Brazil and Mexico.

With the growth of the personalised medicines market, use of e-recruitment methods will tend to grow to reach the targeted patients.

Looking into e-recruitment from the patient's perspective, more than 38 % of the patients get know-how about recruitment status for a trial through search engines such as clinicaltrials.gov, followed by health associations such as NHS, referrals and social media contributing around 8 %.



Source: Centerwatch Online Patient Survey 2012-2013

Although social media is preferred by 8% globally, patients in developed markets have faster adoption of social media compared to those in emerging markets who mostly identify recruitment areas through referrals.

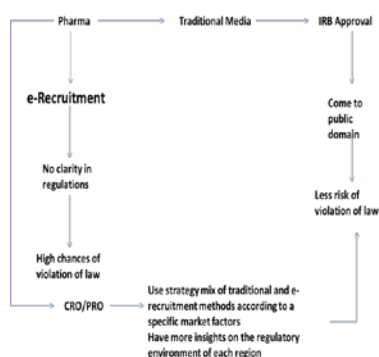
Hurdles for e-patient Recruitment in Emerging Markets

Among the emerging markets, Latin America provides more regulatory freedom as compared to Asia, the Middle East and Eastern Europe. China provides a good friendly market for the use of e-recruitment methods but limited internet access reduces its use.

Countries	Hurdles and Level of impact		
	Regulations	Literacy	Internet access
Argentina	High	Medium	Low
Brazil	Medium	Medium	Low
Colombia	Medium	Medium	Low
Mexico	Medium	Medium	Low
China	High	Medium	Low
South Korea	High	Medium	Low
Israel	High	Medium	Low
Turkey	High	Medium	Low
Bulgaria	High	Medium	Low
Hungary	High	Medium	Low
	High	Medium	Low

Source: <http://www.centerwatch.com>; worldbank.org

Regulatory Challenges:



In the flowchart above we have explained how the e-Recruitment process can overstep the need of IRB approvals for the trial. In traditional methods, sponsors need to get IRB approval for the trials whereas in the case of e-recruitment, companies might not get IRB approvals for the trials. Some partners may overstep this process. This may put the whole clinical study at great risk because in the latter cases the regulatory bodies can question the validity of the trial. In this case the sponsor will be forced to stop the clinical trial in some geography which can backfire on the overall processes. Hence companies need to work on this on a case-by-case basis, and they need to be very careful that their partners (CRO/PRO) have taken all necessary steps before using the e-Recruitment process.

Other hurdles include internet access, technology base, dynamic regulations in emerging markets, disease awareness, etc. Pharma sponsors and trial partners should consider each country as a different situation for their patient recruitment planning and execution.

Case Studies

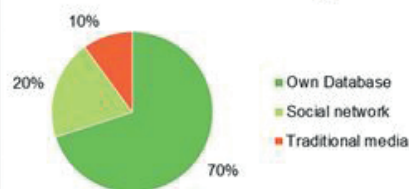
Quintiles

Latin America	Print media	Databases	Advocacy groups	Internet advertisement
Argentina	x	✓	✓	x
Mexico	✓	✓	✓	✓
Brazil	x	✓	✓	✓
Comments	According to Quintiles, Recruitment Strategy mix largely depends on three parameters: Regulations, culture and Healthcare system Quintiles has one of the largest online database MediGuard.org containing details of 2.6 million consumers			

Source: *Company website*

Acurian

Acurian's Recruitment Strategy Mix



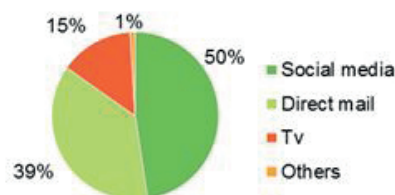
Source: <http://archive.fortune.com>

Pricing Model (Cost per Acquisition)

Price is charged for only the randomised patients who can be used in the trial. This saves the cost of prequalification for the pharma company.

Case Study – Diabetes Phase III Trial

e-Recruitment Methods Used



Source: *Company website*

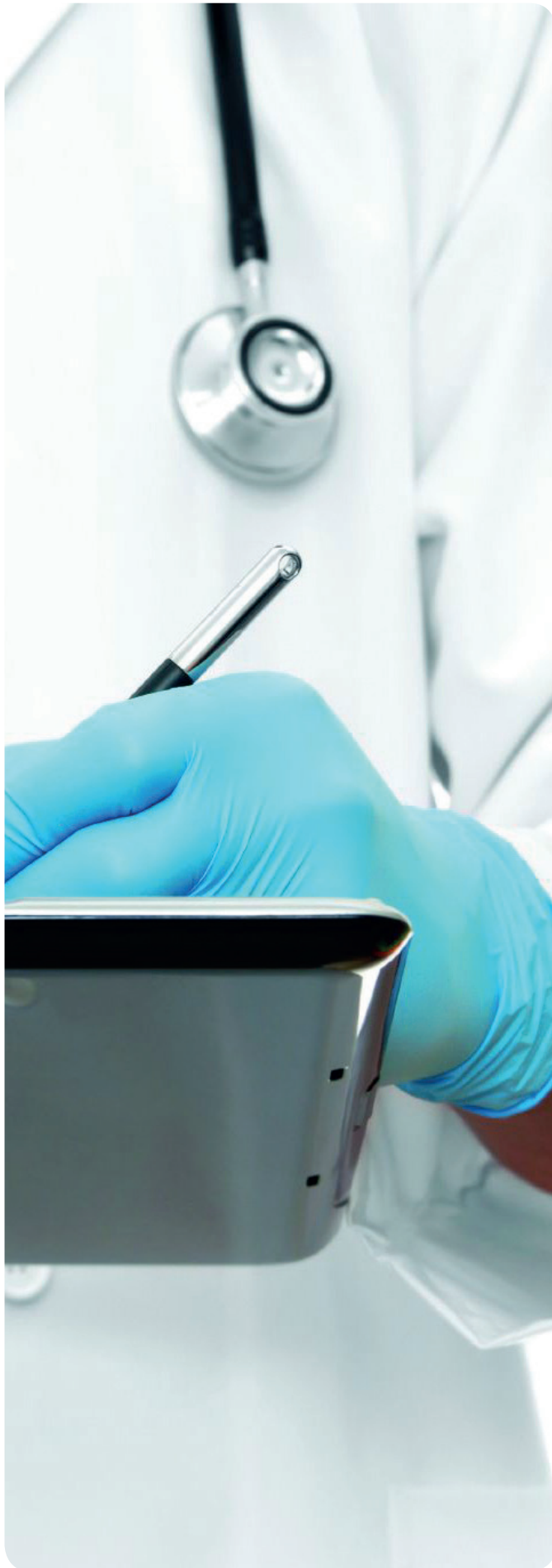
Acurian used social media for patient recruitment in 18 studies in 2009. In a similar type of study, Lilly observed a cost saving of 10% in using digital media over traditional recruitment methods in a pilot study for cancer and diabetes.

According to Mr Scott Connor, Acurian's vice president of marketing, use of Google ads for patient recruitment is less promising and therefore Acurian does not use Google ads in their strategy mix unless it is requested by the client.

BBK Worldwide

Countries	Print media	Community outreach/ Site ambassador	Investigator referrals	Databases
Israel	✓	✓	✓	✓
Hungary	✓	✓	✓	✓
Comments	In Hungary CROs can recruit patients only through PROs, Healthcare providers or sponsor			

Source: *Primary interaction, Beroe Analysis*



Conclusion

Digital media cannot currently be accepted as the exclusive method of patient recruitment in both developed and emerging markets. However, the proportion of its use in emerging markets may tend to rise in future with the changing demography, regulatory and cultural environment of these regions.

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