



# NEW TRENDS AND STRATEGIES FOR PATIENT RECRUITMENT

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# Overview of Discussion



1. Patient Recruitment and Retention Challenges
2. Factors impacting on Patient Recruitment
3. Expanding Web of New Trends and Strategies in Patient Recruitment
4. Implications
5. Conclusion

# Patient Recruitment Challenges



The ability to recruit and retain motivated, informed, protocol-eligible patients starts with sites

Cost to initiate a site costs approximately \$20,000-\$30,000<sup>2</sup>

In 2014, 65% of sites surveyed have less than 3 months **operating cash**

Over the last 15 years, 86% of studies failed to recruit **on time**

11% of sites fail to enrol a single patient; 37% under enroll<sup>1</sup>

39% meet enrolment targets and 13% exceed<sup>1</sup>

Cost to maintain a site is approximately \$1,500 per month<sup>3</sup>

Time, Resources, Cost

# Key Patient Motivators



- Access to medical care
- Patients appreciated the regular follow up they received as trial participants
- Receive medication, which they could otherwise not afford
- To learn more about their disease
- To further the scientific understanding of their condition

# Why Patients won't enroll in a Clinical Trial



- In some countries the industry has a poor reputation,
- Perception of being a “guinea pig”,
- Bad press,
- Fear of side effects,
- Concern over non-treatment (placebo arm),
- Complexity of treatment,
- Payment issues,
- Alternative, satisfactory treatment available,
- Family/work responsibilities,
- Ignorance about clinical research (less than 20% of people are aware that research is an option).



# What is Patient Centricity?



Putting the patient as the most important consideration in every decision we make

Empowering patients to make best decisions for themselves

Understanding individuals living with a disease: their condition, social context, culture and their biases

Listening to patients: Patient focused drug development

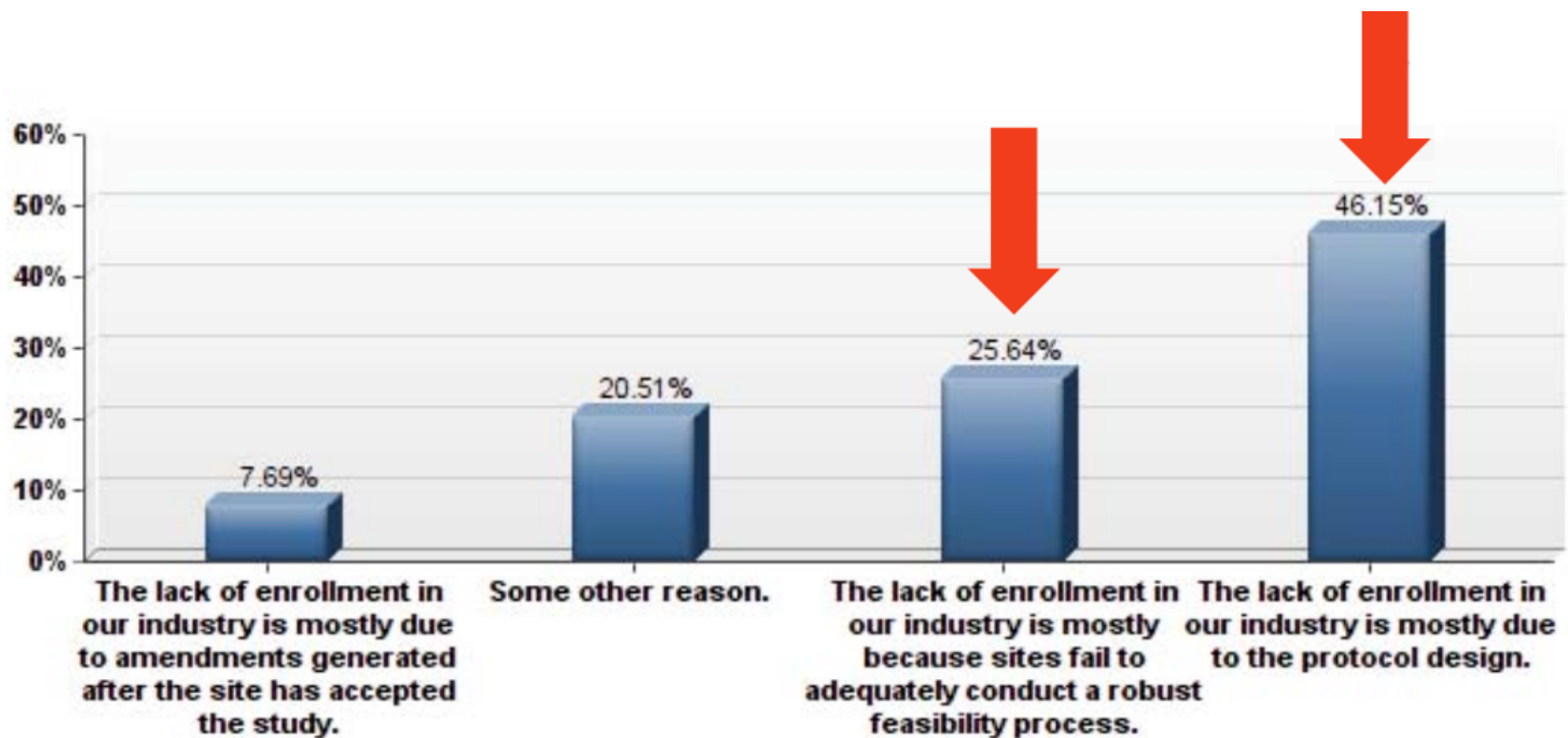


# Factors impacting on Patient Recruitment



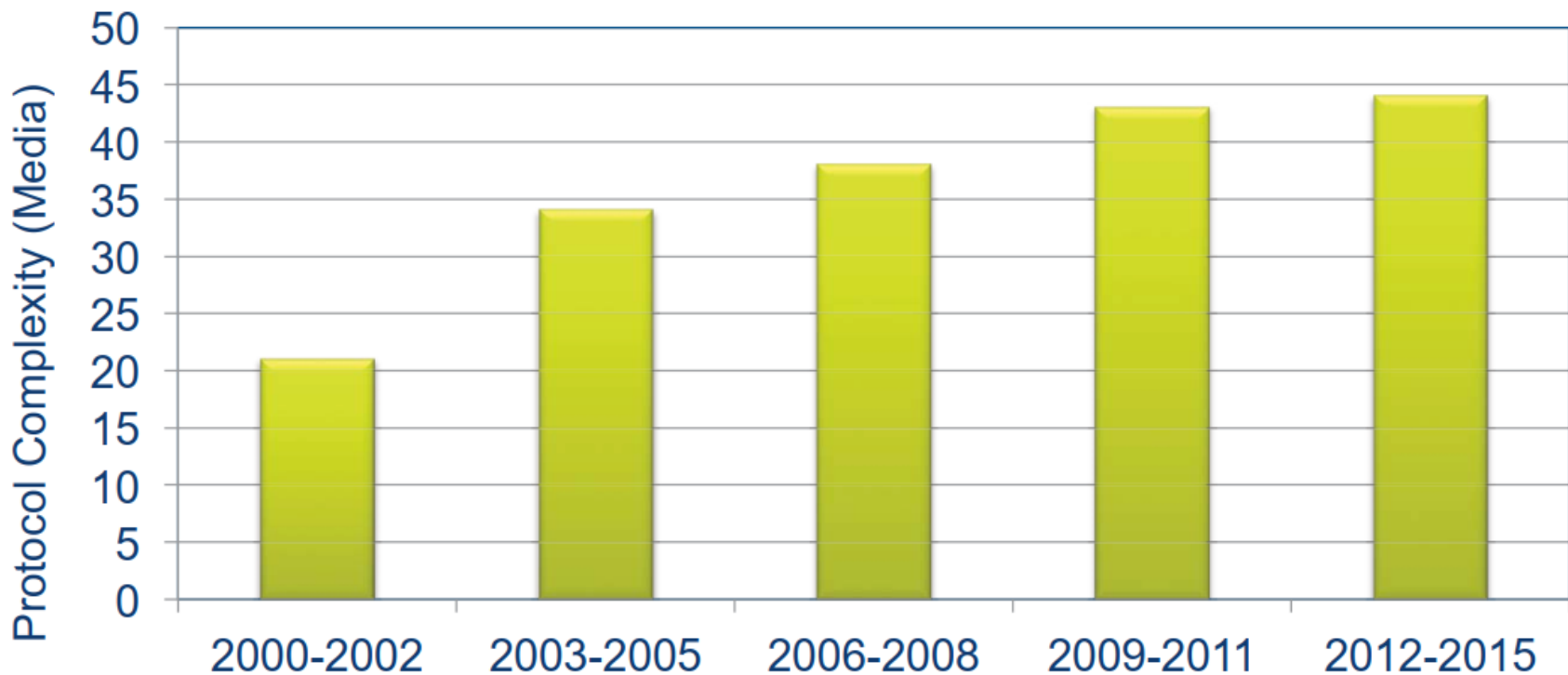
- Type of study
- Protocol design, inclusion/ exclusion criteria
- Barriers to the study
- Accurate feasibility and trial site selection
- Delays in Mandatory approvals
- Unsatisfactory project management & logistical issues
- Contract delays
- Recruitment timeline
- Recruitment budget available
- Competition for patients
- Coping with responses and scheduling of patients
- Screen failure rate
- Planning and tracking, understanding the challenges

# Protocol design & lack of proper feasibility





# Protocol complexity



Source: Medidata - N = 8275 studies, phase II & III, all TAs

# Site Feasibility



- Did the site assess feasibility on draft or final protocol?
- If draft – did sponsor share final protocol and changes between feasibility version and final with site?
- For in-/exclusion criteria changes, was feasibility reassessed?
- If site recommended changes, did sponsor care to consider comments?
- Did sponsor share important feedback that could impact feasibility assessment, received from sites with other sites?
- Sites: Did you spend enough time on the feasibility exercise?

# Is study easy or difficult to execute?



- PK profiles to be done
- Long visits for the patient with many procedures
- Blinded dispenser
- IP – invasive/cultural issues
- Not all sites are equipped to do difficult studies – did you select the right site for your complex study?

# Delays impacting on enrolment timeline (cont)



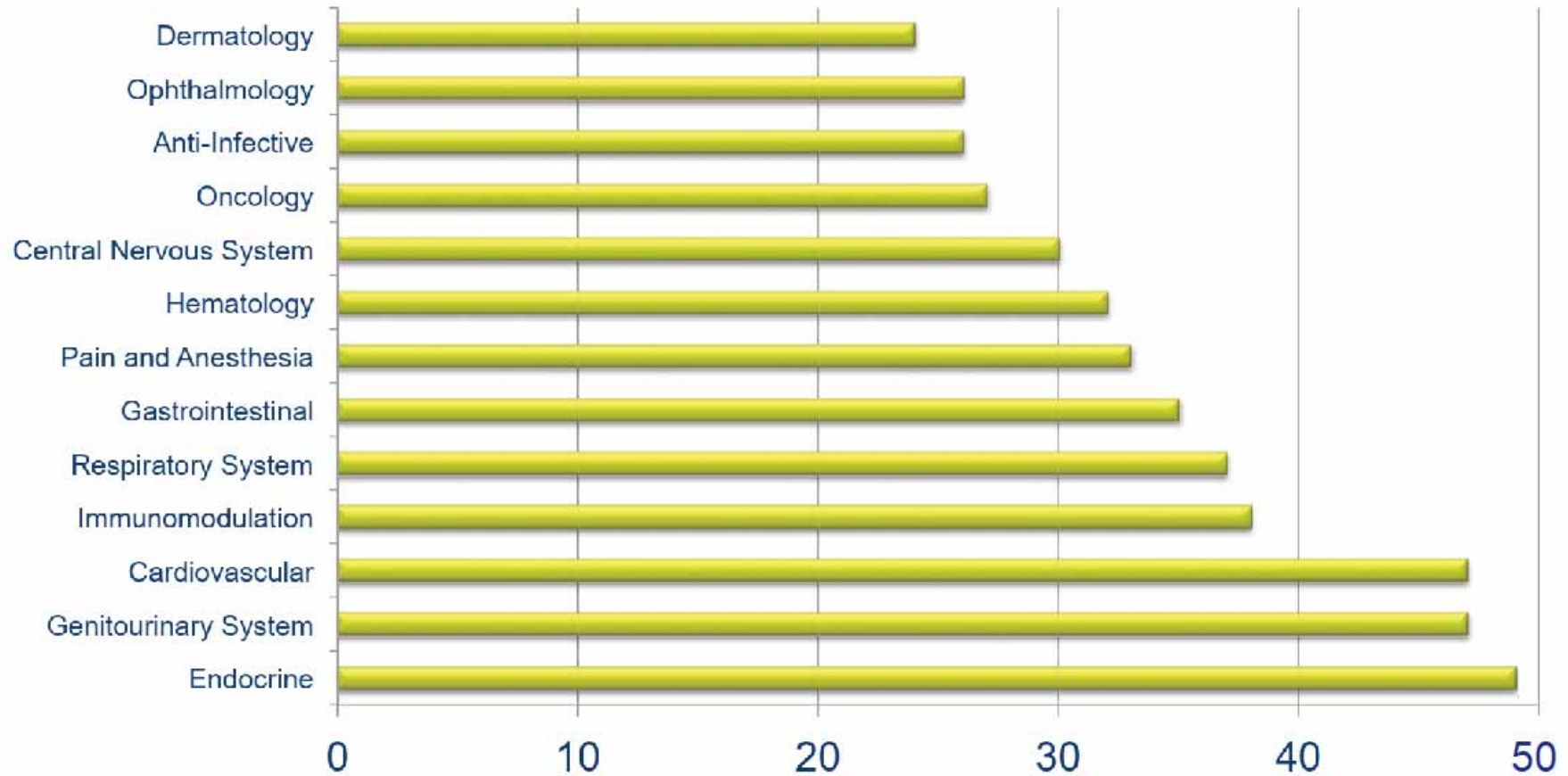
- *Delays in Mandatory approvals*
- *Contract delays*
- *Failure to pay attention to all the logistical issues before SIV and enrolment*
  - Training links site staff not received in time; long electronic trainings to be completed
  - All required translations of Informed Consent
  - IP delays
  - Issues with lab kits and IVRS access
  - Wrong site orders
  - Lab reports not available

# Other Factors impacting on Patient Recruitment



- Recruitment timeline
- No Recruitment budget available to sites
- No patient- focussed recruitment plan
- Competition for similar patients
- Coping with responses and scheduling of patients
- Planning and tracking, understanding the challenges
- Screen failures

# Screen Failure Rate by Therapeutic Area



Source: Medidata Enrollment closed, studies > 10 sites, N = 657 studies, phase II & III, all TAs



# Where will you find your trial participants?



## Outreach by “Pull” Method

*Relies on patient population at the site(s)/Database at the site*  
In- office recruitment.

## Outreach by “Push” Method

May be done through:

- Community Based Recruitment
- Media Strategies (Radio, TV, Print, Billboards, Online)
- Social Media
- External Services (Recruitment companies/Patient Networks/On line Platforms matching patients to trials)

**ALL ADVERTISING MATERIAL TO BE APPROVED BY ETHICS COMMITTEE**

# In Office Recruitment



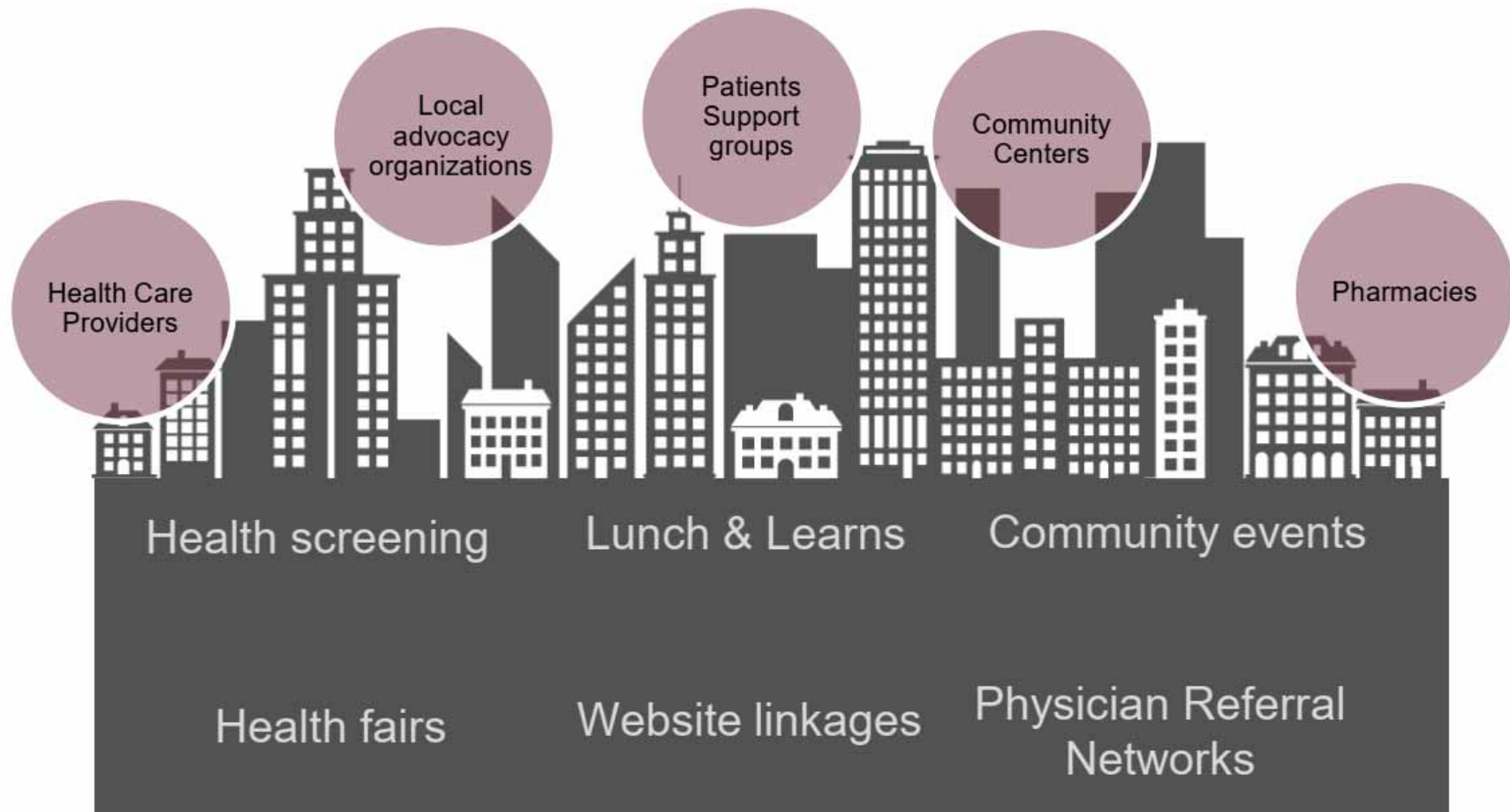
## Tools

Database  
Brochures  
Flyers  
Banners  
Referral cards  
What else?

## Tactics

Database review  
Calling patients  
Bulk SMS  
Emails to patient  
Patient waiting areas  
What else?

# Community Based Recruitment



# Advertising Strategies



- Radio
- Print
- Community TV Stations
- Billboards
- Digital
- Social Media
- Search Engines
- Support group websites
- Blogs
- Institutional/hospital websites

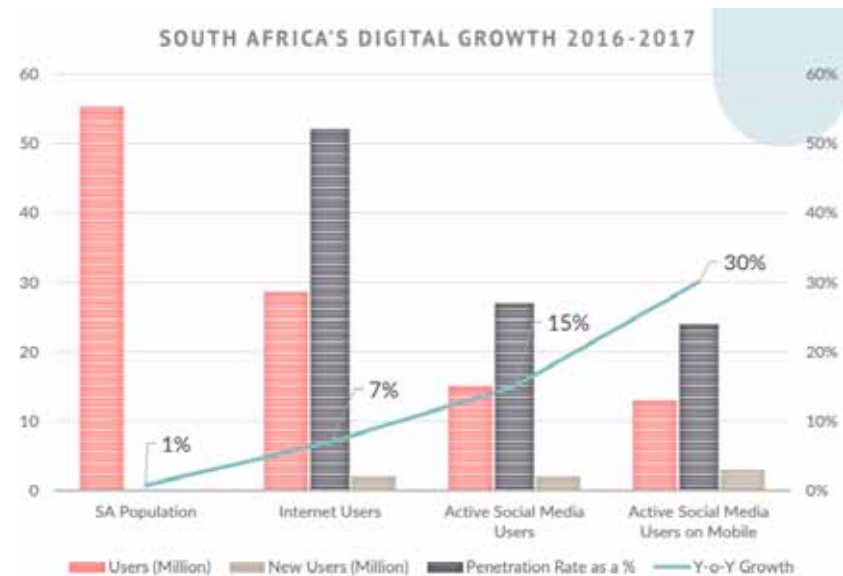
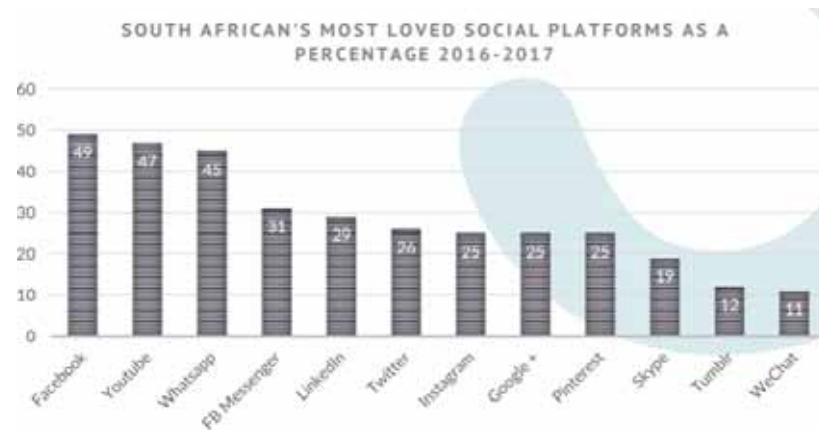
# Planning Your Social Media Strategy



Social media goals:

- Have INTERACTIONS with your audience
- Bring people VALUE

Determine your focus  
Facebook just can't be ignored



# External Services: Patient Recruitment & Patient Network Services



Acurian

Antidote

AutoCruitment

BBK Worldwide

Clariness

ClinicalConnection

ClinLife

CSSi

ePatientFinder

SMOs with significant recruitment capabilities

MMG

Praxis

SubjectWell

StudyKik

ThreeWire

Trialspark

TrialX

plus many more...



# The Study-Specific Patient-Focused Enrolment Plan



Look at previous successes

What are the specific tactics you plan on deploying?

- In office (data base) or own patients at practice
- Community
- Advertising
- External

Pacing and Timing each initiative

Budget

# Implications for accelerated enrolment



1. Implement Patient Centricity in clinical trials,
2. Continue educate communities about clinical research,
3. Do thorough and accurate feasibilities,
4. Minimise clinical trial delays,
5. Have a customised enrolment plan for each study (and budget),
6. Sponsors to fund recruitment activities at sites,
7. Use a diversity of recruitment outlets,
8. Sites: pre-identify patients to build a funnel,
9. Increase expected in patients “pushed” into clinical trials,

## Implications of accelerated enrolment (cont.)



10. Sponsors and Sites: stay on top of current recruitment strategies and learn which activities have best return on investment,
11. Patient Recruitment Companies and Patient Networks: craft marketing messages which resonate with customers,
12. CROs: have a strategy for optimising patient recruitment,
13. Innovative platforms/registries to match patients to clinical trials.

# Summary



No single change will accelerate patient enrolment on its own, but with many innovative/synergistic efforts, sponsors, CROs, SMOs and Sites can continue to improve process efficiencies and expedite time to market for potential life-enhancing products.



**THANK YOU.**

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