



**PRIMEDIA** *PRS*

Patient Recruitment Solutions

On Budget. On Target. On Time.

Expertly **NAVIGATING** clinical trials through traditional, mobile, and digital media & marketing **SOLUTIONS**.

# Services & Capabilities



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# About UAS



○○○○○ [ LET'S DIVE IN... ]

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# SIZZLE REEL





[ THE PriMediaPRS TIES ]

# OUR STRUCTURE



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steve@primediaprs.com

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## We're a true virtual agency...

With a core group of seasoned professionals at the helm. We responsibly manage overhead by maintaining the ability to expand and contract as the workload demands—50-500 of the RIGHT people.

Our trusted partners are the most qualified and strategically experienced—helping us deliver the best, most cost-effective results.



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[ THE PriMediaPRS PERSPECTIVE ]

# OUR EXPERIENCE



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## Successfully navigating clinical trials.

Our in-depth partnerships with companies, such as the ones represented here, has expanded, solidified, and showcased our expertise of the trials process.



[ THE PriMediaPRS COLLABORATIVE ]

# OUR EXPERIENCE

## Our partnerships give us range...

They have allowed us to expand our expertise, covering an impressive spectrum of medicinally treatable diagnoses. Everything from A to U has come through our doors... *and we're working our way to Z.*

- **Acne**
- Alcohol Dependency
- Allergies (Seasonal)
- Alzheimer's Disease
- Anxiety
- Atopic Dermatitis
- Arthritis
- Asthma
- Baldness
- Bipolar Disorder
- Blood Collection
- Breast Disease
- Bunionectomy
- Canker Sores
- Child Psoriasis
- Crohn's Disease
- COPD
- Dandruff
- Depression
- Depression/Pain
- Diabetes (Type 2)
- Dry-eye
- Elderly Depression
- Elderly General Anxiety Disorder
- Elderly Flu
- Eczema Flu
- Essential Tremors
- General Anxiety Disorder
- GERD
- Grass Allergy
- Hay Fever
- Heartburn
- Heroin Addiction
- High Blood Pressure
- High Cholesterol
- Hormone Replacement Therapy
- Hot Flashes
- Hypertension Insomnia
- Major Depressive Disorder
- Menopause
- Mild Cognitive Impairment
- Migraines
- Multiple Sclerosis
- Obesity
- Opioid Use Disorder
- Osteoarthritis
- Perennial Seasonal Rhinitis
- Plaque Psoriasis
- Psoriasis
- Psoriatic Arthritis
- Rosacea
- Schizophrenia
- Sexual Dysfunction
- Social Anxiety
- Social Phobia
- Somatic Depression
- Ulcerative Colitis
- **Urinary Tract Infection**





[ THE PriMediaPRS EDGE ]

# OUR RECOGNITION



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## OK... we're ringing our own bell!

Experience is one thing. But when you've got over over 30 International ECHO and NEDMA awards for creative excellence and results to back it up, we think it's something worth sharing.





*What We Do*



[ CHARTING A NEW COURSE ]

# OUR NEW METHODOLOGY



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## We have a unique way of doing things...

For starters, we don't wait to spend on patient recruitment. The sooner you get the pool of patients you need for the trial, the more time you save over the course of the trial's lifecycle.

We achieve this faster pace, in part, by minimizing our reliance on site-based resources—turning our energies instead on targeting specific locations. This allows us to hyper-focus on securing quality participants.

The 'one size fits all' approach created by the Centralized Agencies is how things used to be. In other words, it's OBSOLETE.

Our results speak for themselves.



# ARE YOU DEPRESSED?

LOCAL PHYSICIANS ARE SEEKING PATIENTS 18 TO 70 YEARS OF AGE, who have been diagnosed with Major Depressive Disorder (MDD), to participate in a clinical research study of an investigational medication for the treatment of Major Depression.

Qualified participants receive all study medication at no charge. Compensation for appropriate time and travel expenses necessary to participate.



**I FEEL** TIRED

- No Longer Interested In Friends
- No Longer Interested In Hobbies
- Not The Same Person I Used To Be

Does this describe you?  
If so, you may qualify for our clinical research program of an investigational medication.

Qualified Participants Receive At No Cost:

• Medical Evaluation	• Study Medication
• Office Visits	• After Study Care



[ PATIENT FACING MATERIALS ]

# SUPPORT SOLUTIONS

When it comes to patient facing support materials, we've got you covered...

- Patient Information Pamphlets
- Inclusion/Exclusion Pamphlets
- Promotional Items
- Flip Charts
- Posters
- Patient ID Cards
- Patient Reminder Cards
- Visitor Reminder Cards
- Patient/Friend Referral Card
- Patient Welcome Letter
- Patient Thank You Letter
- Study Brochure
- Dosing Instructions Card
- Educational & Instructional Videos



SEE YOURSELF IN AN INVESTIGATIONAL STUDY




Let's Face **ACNE** Together!




To qualify, you must be:

- 9 years of age or older
- Have moderate to severe acne vulgaris
- Have a minimum of 20-50 inflammatory papules and pustules face, 25 to 100 non-inflammatory lesions and no more than 2 nodules.



Do you have  
**Relapsing-Remitting  
Multiple Sclerosis?**

You may be eligible to help  
evaluate an experimental  
RRMS drug as part of  
the **EVOLVE-MS-1** study.



[ DOCTOR FACING MATERIALS ]

# SUPPORT SOLUTIONS

And when it comes to doctor facing support materials, we've got that covered too...

- Flowcharts
- Pre-Screen Scripts
- Protocol Books
- Physician Flyer
- Inclusion/Exclusion Pocket Card
- Schedule of Events Form
- Instructional Videos





[ PUBLIC FACING MATERIALS ]

# SUPPORT SOLUTIONS

With everything we've already got covered, we'll still make sure your ready to face your public...

- Doctor's Office Slideshows
- Recruitment Websites
- Pre-Screen Websites
- TV Ads
- Radio Ads
- Print Ads
- Posters
- Poster with Tear-off
- Transit Ads
- Out of Home Ads (Traditional)
- Out of Home Ads (Non-Traditional)
- Digital Display Ads
- Social Media Ads
- SEM/Google Ads
- Pre-Roll Video



**GO NOW!**  
CONSIDER JOINING OUR DEPRESSION STUDY

All eligible study participants may receive at no cost:

- CONSULTATION WITH STUDY DOCTOR
- STUDY DRUGS
- STUDY-RELATED CARE AND VISITS

Have you tried different depression medications and not received adequate symptom relief?

Then, scan the QR code, hop on the Blue line to the Decatur Station, and take yourself to our investigational study NOW!

GO TO A LOCATION NOW





[ TRADITIONAL MEDIA ]

# MEDIA BUYING SOLUTIONS

Traditional media buys play a big role in acquiring quality participants for a given trial. To guarantee we reach the widest and most accurate audience, we utilize outlets such as:

- Network & Syndicated TV
- Spot TV (Local)
- Syndicated TV
- Out-of-Home (OOH)
- Billboards/Bulletins
- Street Furniture (Benches, Kiosks, etc.)
- Network Radio
- Terrestrial Spot Radio (Local)
- Magazine (B2B/Consumer)
- Digital OOH
- Print (National, Local, Specialty)
- OOH Station Dominations
- National Cable Spot
- Cable (Local)
- Transit (Rail & Buses)
- Direct Mail
- Direct Response (Short and Long Form)
- Airports/Taxi

## Help us put **MS** to the test.



DO YOU HAVE RELAPSING – REMITTING MS?

We're conducting a clinical study of an investigational drug and need your help. If you qualify, you will meet with a study doctor and receive the investigational drug and study-related care at no cost to you.



**Still feeling BLUE?**

### We're taking a different approach to depression.

If you've tried depression medications and they haven't worked very well, you're not alone. We're developing an investigational drug designed to work along with your antidepressants to see if it can help address unresolved symptoms. Please consider joining this investigational study. As long as you're 18 years of age or older, you may be eligible to participate whether or not you are currently taking an antidepressant.

All eligible study participants may receive at no cost: **CONSULTATION WITH STUDY DOCTOR** **STUDY DRUGS** **STUDY-RELATED CARE AND VISITS**





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[ DIGITAL MEDIA ]

# MEDIA BUYING SOLUTIONS

When it comes to our digital media buys, we like to take full creative advantage of the vast opportunities available. Here are just a few of the potential locations you can expect us to target:

- Search Engine Marketing (SEM)
- Email Newsletters
- Programmatic Video & Display (Pre-Roll)
- Advanced TV
- PBM (People Based Marketing)
- Display (Desktop/Mobile)
- Blogs
- Mobile in App
- Connected TV
- Over the Top (OTT)
- Social Media (Facebook, Twitter, etc.)
- Email Retargeting
- YouTube
- Craigslist
- Digital Radio (Pandora, iHeart, Spotify)





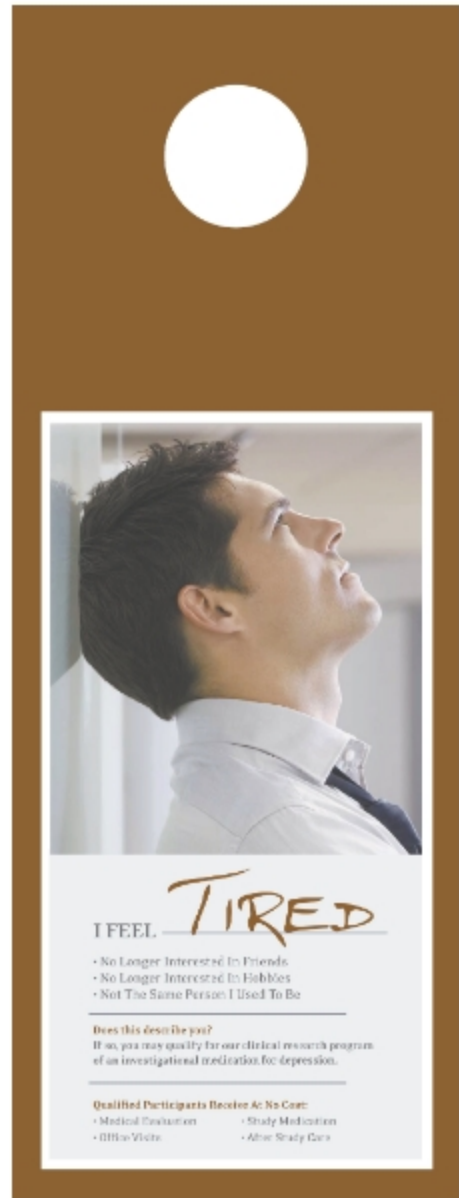
[ NON-TRADITIONAL MEDIA ]

# MEDIA BUYING SOLUTIONS

As important as our traditional and digital media buys are to the clinical trial process, it's how we implement non-traditional media that helps us shave so much time off the patient acquisition period.

- Doctor's Offices (Posters, In Office TV)
- Elevators
- Aerial
- Guerilla Marketing
- Pizza Boxes/Food Containers
- Health Clubs
- Cinema Advertising
- Bar/Restaurant Advertising (Coasters/Posters/Restrooms)
- Geo-Tracked Door Hangers

- Experiential/Street Teams
- Convenience & Grocery Stores
- Ferry Advertising
- Pharmacy (Bags, Floor Decals, Take Ones)
- Window Clings
- Malls
- Gas Pump Toppers
- In Stadium
- Truckside



A photograph of a sailboat's deck on the left side, with the ocean and a sunset in the background. The sun is low on the horizon, creating a warm orange and yellow glow. The text "Our Results" is written in a white, cursive font across the middle of the image. The boat's deck features a circular logo with a lightning bolt and a square, and several orange buoys are visible.

*Our Results*

# DATA & RESEARCH

At PriMediaPRS we strive to plan and place the most efficient and effective schedules on behalf of our clients—yielding the best results.

In order to accomplish this, we use Nielsen Media Research data & ratings to quantify radio, TV, cable, and web viewership to make sure clients get their messages in front of the right audiences. We use SQAD & Kantar Media data both to make sure that our media rates remain competitive as well as keep the right mix moving forward.

Research supplied by 3rd party suppliers like The Media Audit, Scarborough, and MRI provide qualitative insights into consumers and their media habits. The FreeWheel Management System allows us to research, plan, place, and post media schedules directly with media vendors.



TV, Cable, Radio & Online Ratings, Data & Research



TV, Radio & Online Rate Data

Competitive Information



Planning and Qualitative Audience Data



Media Buying Software for Quantitative Research, Media Planning, Buying & Posting.



# DATA & RESEARCH

## Digital/Mobile Data Suppliers...

In addition, we incorporate dozens of data provider's proprietary information on media consumption when we place digital/mobile media on our client's behalf, enabling highly accurate online targeting.

All while staying completely HIPAA compliant.





[ TACTICAL ALLOCATION ]

# COST SAVINGS EXAMPLES



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As a virtual agency, PriMediaPRS is structured to save our clients money.

Meanwhile traditional agencies continue to coerce companies into spending large sums for what amounts to fractions in return.

<b>Budget A: Tactical Allocation*</b>	
<i>Approved by Client on October 14, 2014</i>	
<b>PLACEMENT</b>	<b>ONLINE</b>
Display/Banner	\$80,000.00
Google SEM	\$50,000.00
Facebook Advertising	\$20,000.00
Streaming Radio	\$50,000.00
<b>TOTAL</b>	<b>\$200,000.00</b>

**\*ACTUAL tactical allocation by large centralized agency**

As shown in this sample Tactical Allocation spreadsheet, these Centralized Agencies make their living burying their administrative costs into your advertising budget.



[ PURCHASING ALLOCATION ]

# COST SAVINGS EXAMPLES



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Large Centralized Agencies are double-dipping, charging \$200k for only \$121k worth of media placement.

We know the agency's commission is at least 15%. Then you can see below that there's \$50k for Project Management, and plenty more. Only 51% of the original \$200k allocated actually goes towards media placement. That's not how we do things.

**\*PROPOSED tactical/purchasing allocations by large centralized agency**

Budget A: Tactical Allocation*	
<i>Approved by Client on October 14, 2014</i>	
PLACEMENT	ONLINE
Display/Banner	\$80,000.00
Google SEM	\$50,000.00
Facebook Advertising	\$20,000.00
Streaming Radio	\$50,000.00
<b>TOTAL</b>	<b>\$200,000.00</b>

**Only 51% of the budget to  
went toward placement! \$97K  
in FEES went to Centralized  
Agency!**



**\*ACTUAL tactical/purchasing allocations by large centralized agency**

Budget B: Purchasing Allocation*	
<i>Approved Media Plan Internal/External Costs</i>	
PLACEMENT	ONLINE
Media Placement Display/Banner Google SEM Facebook Advertising Streaming Radio	\$120,965.00
Media Planning	\$39,002.49
Media Buying	\$19,031.18
Media Distribution	\$6,000.38
Media Tracking & Reporting	\$15,000.96
<b>TOTAL</b>	<b>\$200,000.00</b>



[ PRODUCTION ]

# COST SAVINGS EXAMPLES



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At PriMediaPRS, we go about budgeting a bit differently.

This table shows how, for the same deliverables and in the same quantity, traditional Centralized Agencies are comfortable charging you \$124,500 more than PriMediaPRS.

DESCRIPTION	QUANTITY	PRIMEDIA COST	CA COST	SAVINGS
Radio Spot Tagging	200			
TV Spot Tagging	200			
:30 TV Spot Delivery	300			
	<b>TOTAL:</b>	<b>\$160,500.00</b>	<b>\$285,000.00</b>	<b>\$124,500.00</b>

\*ACTUAL production comparison

**44% savings on Production!**

And this isn't the only evidence of our money-saving prowess...



[ ANALYTICS ]

# COST SAVINGS EXAMPLES



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We guarantee we save our customers money by utilizing SQAD media tools to measure exactly where our pricing rests among the rest of the industry.



SQAD brings transparency to the media marketplace by providing independent third-party media cost data, forecasting, and planning solutions. Their rating system (high, medium, low) takes into account all 125 markets nationwide.

**PriMediaPRS sits comfortably in low SQAD, meaning more of your money—and time—is saved.**



[ BROADCAST MEDIA ]

# COST SAVINGS EXAMPLES



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The example below shows that PriMediaPRS saves you an additional 54% when compared to the average costs provided by SQAD.

MEDIA	PRIMEDIA SPEND	SQAD COST	SAVINGS
Q1 TV	\$169,935.00	\$472,699.10	
Q1 Radio	\$11,315.00	\$21,938.60	
Q2 TV	\$479,620.00	\$1,086,505.70	
Q2 Radio	\$182,750.00	\$258,600.50	
<b>TOTAL:</b>	<b>\$843,620.00</b>	<b>\$1,839,743.90</b>	

**\*ACTUAL TV & Cable SQAD Report**

**That's nearly \$1,000,000.00 in this case!**



For this media buy, the Average SQAD cost is \$1,839,743.90. In comparison, the PriMediaPRS cost is a much lower \$843,620.00. That saves you an unbelievable \$996,123.90!

And while saving money is great, it's only a piece of the actual value that we provide...



[ DIGITAL MEDIA ]

# COST SAVINGS EXAMPLES



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In addition to all the money that PriMediaPRS saves for our clients, we also deliver effective campaigns that continually outperform industry standard benchmarks.

Q1 SUMMARY		
Impressions	Clicks	CTR
174,791	284	0.162%
Q2 SUMMARY		
Impressions	Clicks	CTR
34,897,283	57,365	0.051%
Q3 SUMMARY		
Impressions	Clicks	CTR
11,590,850	42,017	0.363%
TOTAL SUMMARY		
Impressions	Clicks	CTR
46,662,924	99,666	0.214%

This example shows one such indicator of that success: the Click Through Rate (CTR) of our digital campaigns from Q1-Q3.

**Over the course of three quarters, we exceeded the National Average CTR by 428%!**

**\*Actual SEM, Social, & Display SQAD Report**

Next, let's see how all this comes together in practice...

# RESULTS [CASE STUDY I]

## Impact and Return on Investment of Patient Recruitment Campaign in a Clinical Trial of Patients with Opioid Use Disorder

Jandira Ramos, M.P.H.<sup>1</sup>, Denise Carter<sup>1</sup>, Stephen Romanello<sup>2</sup>, Matt Miller<sup>3</sup>, and William Martin, Ph.D.<sup>1</sup>

<sup>1</sup>Alkermes, Inc., 852 Winter Street, MA 02451 USA, <sup>2</sup>PriMedia, 1775 South Hill Road, Warwick, RI 02886 USA, <sup>3</sup>StudyKIK, LLC, 1675 Scenic Ave #150, Costa Mesa, CA 92626 USA

### INTRODUCTION

ALKERM-002 was a Phase 3 clinical trial that evaluated the efficacy, safety, and tolerability of low doses of oral naltrexone used in conjunction with sublingual buprenorphine (BLU) for adults with opioid use disorder (OUD) transitioning from OUD maintenance therapy (BMT) or to the first application of VIVITROL (mefenorexone for extended-release naltrexone) for extended-release naltrexone suspension.

Recruitment of patients with OUD is a challenging and complex endeavor in a clinical trial setting. Similar to other disease areas, a common dilemma in this population is the concern of reaching placebo. However, there were several unique factors that served as barriers to enrollment of this patient population in the present trial. For example, many OUD providers are reluctant to refer patients to a clinical study, especially when there is a requirement to taper patients to lower BMT doses.

Additionally, given that many patients are maintained on buprenorphine doses greater than 8 mg, a unique challenge of this trial was identifying a protocol-specific target population of OUD-maintained patients on an entry dose of only 8 mg. Given these challenges, the present trial required innovative patient recruitment strategies that were implemented over the course of the trial.

Recruitment challenges included:

- Private Practice/Community Outreach Local Referrals (Dr. to Dr Letter Study and VIVITROL brochures)
- Advertisements:

  - Interactive site input on types of ads proved effective in their geographic area for previous trials (ALKERM-001)
  - During the course of the trial, shifts were made as needed to ensure only effective advertisements are needed.

### RESULTS

FIGURE 1: Recruitment Source - Screened Subjects

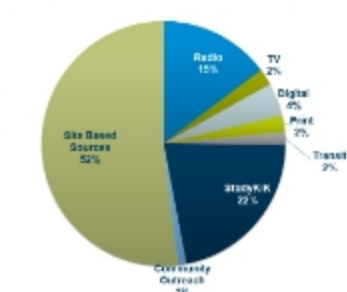


Figure 1. Of the 183 patients screened between January-October 2017, it is estimated that 48% of patients came from the PRC efforts. As the trial progressed, site-based sources, with radio and StudyKIK, accounted for almost half of the recruitment by the end of the trial.

FIGURE 2: Recruitment Source - Randomized Subjects

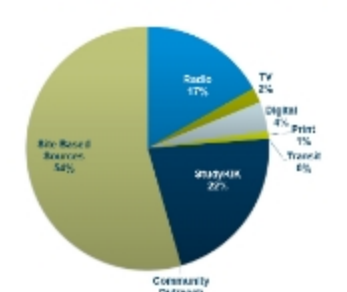


Figure 2. Of the 101 patients randomized, it is estimated that 46 of 101 (46%) patients randomized came from PRC. Out of the 58 patients randomized at the end of the trial (August - October 2017), 17 patients came from site-based sources and PRC made up the rest. As site-based sources became exhausted half way through the study, StudyKIK made up 22% of the randomizations at the end, 17%.

FIGURE 3: Randomization from advertisements

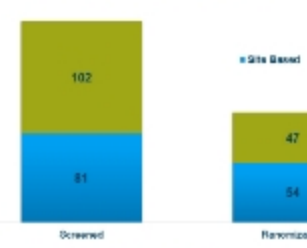


Figure 3. Based on recruitment source from IRT, of the 183 subjects screened 102 (56%) came from PRC. Out of the 101 randomized 47 (47%) came from PRC.

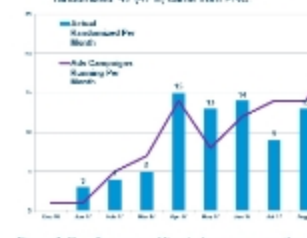


Figure 4. Over the course of the study, as more recruitment campaigns were added (traditional methods and StudyKIK), the rate of randomizations per month increased in the subsequent weeks. This was particularly evident towards the end of enrollment period where there was a final push for advertisement.

### METHODS

**Key study design elements:**

- The study was 36-weeks in duration and included a 9-12 day inpatient BUP taper/cessation with naltrexone challenge and VIVITROL administration on Day 8.
- Patients (N=52) were randomized in a 1:1 ratio to 1 of 2 treatment arms consisting of ascending doses of oral naltrexone and BLU or placebo naltrexone and BLU.
- Patients were stratified according to low (8mg/day) versus high (16mg/day) BUP maintenance dose at the time of initiation of a BUP Lead in period (5 day stabilization on 8mg/day BUP). All subjects received a standardized ancillary medication regimen.

**Patient Recruitment Campaign (PRC) Strategies:**

- Location-based Out-of-Home (OOH) advertising to target major BUP providers in each metropolitan area.
- Utilized StudyKIK, a company that connects people to local clinical trials through social media communities.
- Continually adjusted campaign language across all advertisements and social media posts to reach patients on BMT. This was critical as opioid addiction vocabulary did not always resonate with patients on BMT, who did not consider themselves opioid dependent.
- Added StudyKIK Patient Messaging Suite feature to facilitate added communication with potential participants in a timely manner.

**Sponsor Oversight and Site Engagement:**

- Recruitment source was captured at the time of screening in Interactive Response Technology (IRT) by the site.
- Weekly site calls to review prescreening metrics and confirm accuracy of recruitment sources in IRT.
- Frequent site visits allowed for assessment of site enrollment expectations, projections, and improvements to site-specific Patient Recruitment plan.
- Publication of site visit/feedback to enrollment (locality/half resource limitations).

FIGURE 4: Recruitment Advertisements



Figure 4. Location-based Out-of-Home (OOH) advertising campaign was created to target areas where major BUP providers were located in each metro area. Specific language was chosen for StudyKIK and social media posts to attract the words "Opioid Dependent" from campaigns and to reflect that BMT was required, since many BMT patients do not consider themselves opioid dependent. Advertisement placements were reviewed regularly for campaign effectiveness.

FIGURE 5: Overall vs. Site Based Enrollment

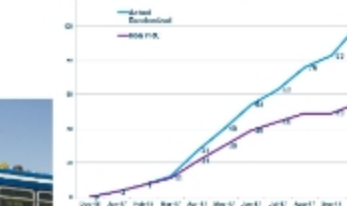


Figure 5. Over the course of the study, it was estimated that without PRC, 55 (54%) patients came purely from site-based sources by the end of October 2017.

FIGURE 6: Overall vs. Projected Site Based Enrollment

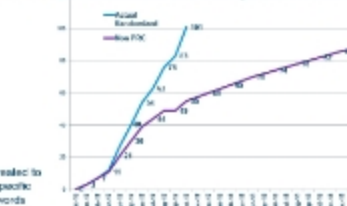


Figure 6. It was estimated that the site-based randomization rate after database exhaustion would be around 3 subjects per month at first and would slowly taper off as the study continued (as was seen in the last half of enrollment). Assuming a monthly enrollment rate of 3-5 subjects per month from site-based resources alone (no ads), it is estimated that it would have taken an additional 20 months to run the study. With an average monthly operational cost of \$250K, the additional 20 months of enrollment is estimated to cost an additional \$5M.

### CONCLUSIONS

**Take-Home Points:**

- Without a novel PRC strategy, meeting the enrollment target of 90 subjects by end of 2017 would not have been met.
- With site resources alone, the trial would have taken an additional 20 months to complete and an additional ~\$5M in operational costs. Sites were selected based on their databases and ability to recruit patients for this study, however, it was not enough to carry through until the end of enrollment.
- Site databases were exhausted half-way through the trial and PRC campaigns made up most of the randomizations through the final months of enrollment (August - October 2017).
- StudyKIK and Radio were the most successful PRCs for this subject population and site locations.



PriMediaPRS was named as an author during a recent trial where we

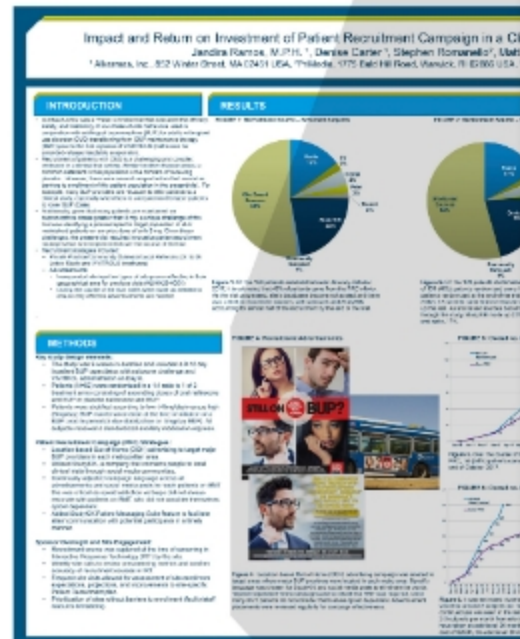
**REDUCED THE OVERALL TRIAL TIME** from the standard 3-5 to 1-3 years.

Let's further explore the PriMediaPRS approach through the results of this trial...



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# RESULTS



**FIGURE 4: Recruitment Advertisements**

**ARE YOU CURRENTLY BEING TREATED WITH BUPRENORPHINE (SUBOXONE®, SUBUTEX® OR BUNAVANT®) AND WOULD LIKE TO BE OPIOID FREE?**

If the answer is yes, you may qualify to take part in a clinical research study.

[INSERT SITE NAME] is conducting an inpatient research study using an investigational treatment to transition individuals ages 18-80 years old from buprenorphine maintenance to an initial dose of VIVITROL® and to manage withdrawal symptoms. Qualified participants will receive study-related medical care at no cost. Participants may also be compensated for time and travel.

**FOR MORE INFORMATION, CONTACT THE STUDY TEAM:**  
[INSERT SITE CONTACT]

**Figure 4.** Location-based Out-of-Home (OOH) advertising campaign was created to target areas where major BUP providers were located in each metro area. Specific language was chosen for StudyKIK and social media posts to eliminate the words "Opioid Dependents" from campaigns and to reflect that BMT was required, since many BMT patients do not consider themselves opioid dependent. Advertisement placements were reviewed regularly for campaign effectiveness.

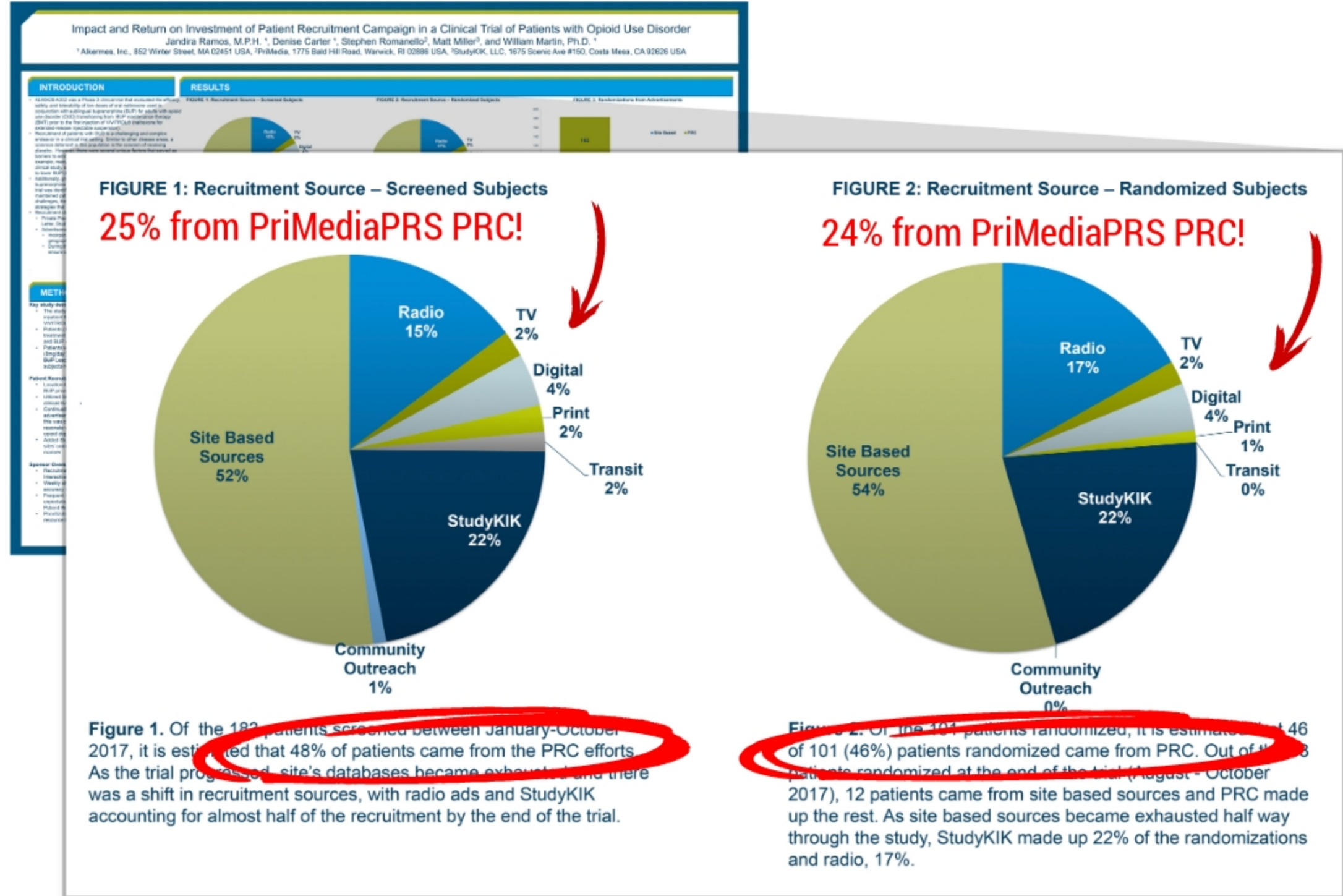
A large part of PriMediaPRS's success is our focus on location-based patient recruitment.

We take advantage of a host of physical and digital media/advertisements to see this through.

Advertisements range from metro areas, to bus banners, social media posts, and much more. Every message is catered to fit its outlet perfectly.



# RESULTS

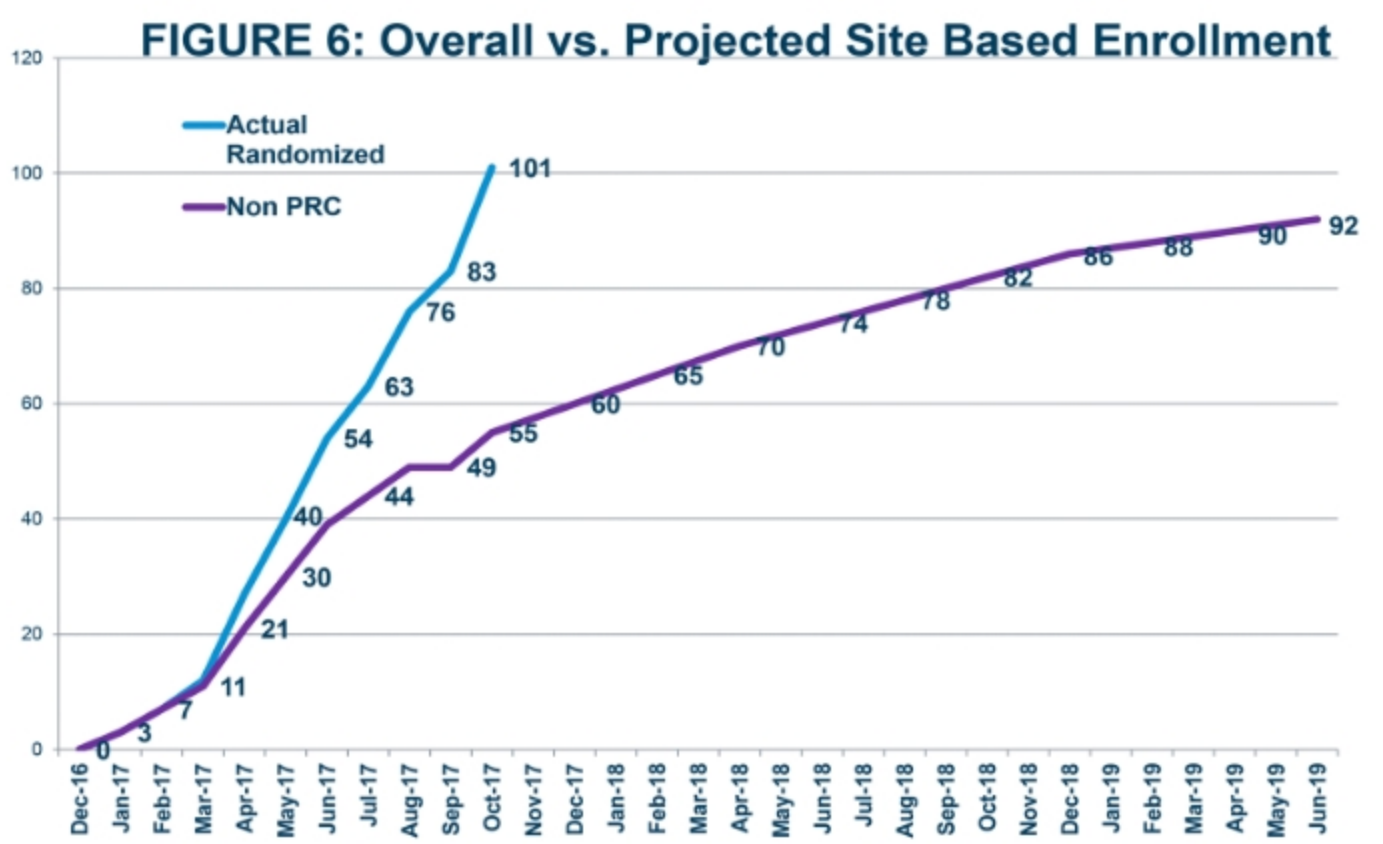


Thanks to our recruitment methods...

We were able to provide 25% of screened subjects, and an additional 24% when it came to randomized subjects for this particular trial.



# RESULTS



**Figure 6.** It was estimated that the site based randomization rate after database exhaustion would be around 3 subjects per month at first and would slowly taper off as the study continued (as was seen in the last half on enrollment). Assuming a monthly enrollment rate of 2-3 subjects per month from site-based resources alone (no ads), it is estimated that it would have taken an additional 20 months to run the study. With an average monthly operational cost of \$250, the additional 20 months of enrollment is estimated to cost an additional \$5M

The amount of time we were able to save was previously unheard of.

Take a look at the difference between projection and actuality. If things went 'according to schedule,' the whole trial period would have run for 20 months, **costing upwards of an additional \$5M.**

**INTRODUCTION**

**METHODS**

**RESULTS**

**CONCLUSION**

**Alkermes**





# CONCLUSIONS

## Take-Home Points:

- Without a novel PRC strategy, meeting the enrollment target of 92 subjects by end of 2017 would not have been met.
- With site resources alone, the trial would have taken an additional 20 months to complete and an additional ~\$5M in operational costs. Sites were selected based on their databases and ability to recruit patients for this study, however, it was not enough to carry through until the end of enrollment.
- Site databases were exhausted half way through the trial and PRC campaigns made up most of the randomizations through the final months of enrollment (August – October 2017).

The final results for this trial paved the way for some interesting revelations...



**CONCLUSIONS**

**Take-Home Points:**

- Without a novel PRC strategy, meeting the enrollment target of 92 subjects by end of 2017 would not have been met.
- With site resources alone, the trial would have taken an additional 20 months to complete and an additional ~\$5M in operational costs. Sites were selected based on their databases and ability to recruit patients for this study, however, it was not enough to carry through until the end of enrollment.
- Site databases were exhausted half way through the trial and PRC campaigns made up most of the randomizations through the final months of enrollment (August – October 2017).

**Figure 6: Overall vs. Projected Site-Based Enrollment**

Figure 6 shows the cumulative enrollment over time. The x-axis represents time in months, and the y-axis represents the number of subjects. Two lines are plotted: a solid line representing 'Overall Enrollment' and a dashed line representing 'Projected Site-Based Enrollment'. The overall enrollment line rises more steeply than the projected site-based enrollment line, indicating that PRC campaigns significantly contributed to meeting the enrollment target.



# RESULTS [CASE STUDY II]

## Impact and Return on Investment of Patient Recruitment Campaign in a Clinical Trial of Patients with Schizophrenia

Denise Carter<sup>1</sup>, Stephen Romanello<sup>2</sup>, Matt Miller<sup>3</sup>, and William Martin, Ph.D.<sup>1</sup>

<sup>1</sup> Alkermes, Inc., 852 Winter Street, MA 02451 USA, <sup>2</sup> PriMedia, 1775 Bald Hill Road, Warwick, RI 02886 USA, <sup>3</sup> StudyKIK, LLC, 1675 Scenic Ave #150, Costa Mesa, CA 92626 USA

### INTRODUCTION

- ALKS301-ASO3 is a Phase 3 study to evaluate the safety and efficacy of a fixed-dose combination of olanzapine and amisulpride (ALKS 3031) compared to olanzapine alone for treatment of adults with schizophrenia (SCZ).
- Historically, the recruitment and rate of enrollment of subjects with schizophrenia in clinical trial settings has been quite variable. For example, inpatient trials of subjects with acute exacerbations of SCZ often enroll quite rapidly, whereas outpatient trials of subjects with stable illness tend to enroll much more slowly. In ALKS301-ASO3, we sought to enroll a challenging population of subjects with relatively stable illness treated in an outpatient setting.
- Key protocol limitations for this population required that patients be of age 18-55 years, have a body mass index of 18-30 and not have recent exposure to clozapine. These criteria were estimated to reduce the number of eligible subjects by more than half.
- Given these challenges, the present trial required patient recruitment strategies, which were implemented over the course of the trial in an effort to increase the rate of enrollment.

### METHODS

**Key study design elements:**

- After the screening period, patients will be randomized 1:1 to either OLZ monotherapy (10 or 20 mg) or ALKS 3031 (10 mg OLZ/10 mg SAM or 20 mg OLZ/10 mg SAM) orally once daily for 26 weeks.
- During the first week, patients will receive 10 mg OLZ per dose daily, either ALKS 3031 10/10 (10 mg OLZ/10 mg SAM) or OLZ 10 (10 mg OLZ), according to treatment assignment. At the end of Week 1, the OLZ dose will escalate to 20 mg; ALKS 3031 20/10 (20 mg OLZ/10 mg SAM) or OLZ 20 (20 mg OLZ).
- In this outpatient study, patients will visit the study site weekly for the first 5 weeks, then every 2 weeks for the remaining 18 weeks.

**Patient Recruitment Campaign (PRC) Strategies:**

- Recruitment strategies included:
  - Branded materials for site-specific community outreach and lunch and learn efforts (Brochures, physician letters, posters, etc.)
  - Vigorous efforts to engage with sites to confirm recruitment/advertising strategies throughout the study via bi-weekly numerous face-to-face meetings.
  - Incorporated site input through recruitment strategies to deploy effective strategies based on location, experience, and what has been proven effective through ROI.
  - During the course of the trial recruitment strategies were continuously assessed for return on investment to ensure timely changes were made to maximize effectiveness.
  - Ongoing Collaboration with PRMedia to ensure traditional advertising (TV, radio, print, etc.) campaigns were tailored to site suggestions.
  - StudyKIK Patient Qualification Suite was utilized to facilitate site response to referrals and reduce the burden of high-volume of patient referrals.

**Sponsor Oversight and Site Engagement:**

- Recruitment source was captured at the time of screening in Interactive Response Technology (IRT) by clinical trial sites.
- Campaign specific site calls were conducted to confirm mid-campaign status/effectiveness and overall pre-screen, screen, and randomized metrics, these efforts allowed us to confirm accuracy of recruitment sources in IRT.
- Frequent site visits allowed for assessment of site enrollment speed/accuracy, projections, and improvements to site-specific Patient Recruitment plan.
- Investigator regional meetings were held regularly to engage with sites, obtain study feedback, share lessons learned, and provide enrollment updates.

### RESULTS

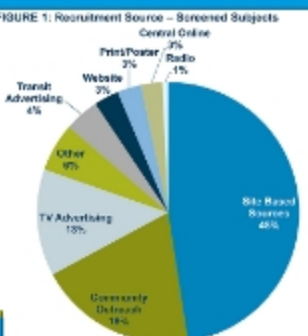


Figure 1. It is estimated that 32% of subjects screened came from the PRC efforts. As the trial progressed, site databases became exhausted and there was a shift in recruitment strategies in order to remain on track with projections accounting for half of the remainder by the end of the trial.

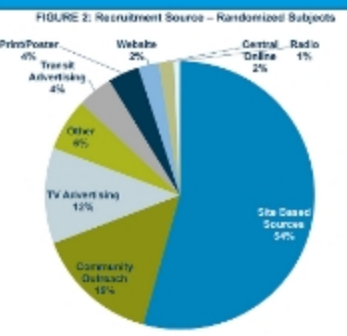


Figure 2. It is estimated that 46% of patients randomized came from the PRC efforts. The PRC efforts were essential in the Sponsor being able to meet enrollment timelines.

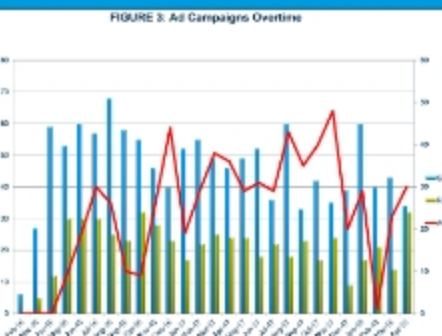


Figure 3. Over the course of the study advertising campaigns were adjusted to ensure effective spots were deployed, make-up for database exhaustion, and deploy effective efforts during non-impactful timeframes such as holidays.



Figure 4. Study branded name, ENLIGHTEN-2 was created to help identify the study and assist with easier access for those interested. Study branding was also implemented to help attract patient and caregiver attention. Additional materials were developed and adjusted overtime to ensure site visits were removed to provide an effective look.



Figure 5. The duration of enrollment was 28 months with an enrollment rate of 0.46 subjects randomized per site per month. It is estimated it would have taken ~15 months longer to enroll the trial if PRC efforts had not been undertaken. Without implementing a robust patient recruitment campaign, the overall trial cost would have been an additional ~\$1M. This amount was calculated by multiplying operational cost of the trial per month by the number of additional months it would have taken to enroll the trial using a robust recruitment source.

### CONCLUSIONS

**Take-Home Points:**

- The PRC strategies deployed in the present trial were essential in meeting the enrollment timeline. Without the PRC, the enrollment target of 540 subjects by April 2018 would not have been met.
- With site resources alone, the trial would have taken an additional 13 months to complete and an additional ~\$1M in overall trial costs. Sites were selected based on their ability to recruit patients for this study and existing database of patients.
- Site databases were exhausted approximately one year into the trial.
- The PRC campaign accounted for the majority of randomizations over the final 28 months of enrollment.
- Community outreach, TV, Travel, and Social Media were the most successful tactics in the PRCs for this subject population and site locations.

### LIMITATIONS

- Although every effort was made to ensure that sites were correctly reporting subject recruitment source, entry errors can not be ruled out. Frequent bi-weekly calls were conducted to assist with source confirmation as well as to remind sites to update source accordingly.



Let's take a look at a second trial example...

Here, same as before, we made a point to invest in patient recruitment early on in the process.



○ ○ ○ ○ ○ [ CASE STUDY II ]

# RESULTS

FIGURE 4 : Recruitment Advertisements



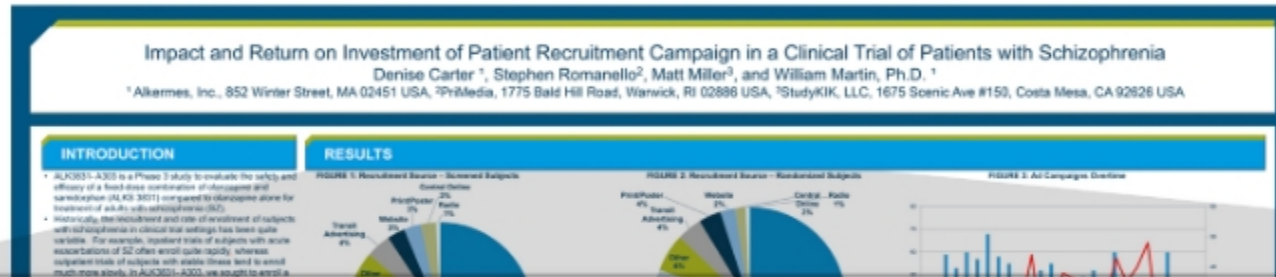
Figure 4. Study branded name, ENLIGHTEN-2 was created to help identify the study and assist with easier access for those interested. Study branding was also implemented to help attract patient and caregiver attention. Additional materials were developed and adjusted over-time to ensure stale views were removed to provide an effective look.

We released our patient recruitment advertisements out into the world...

With an emphasis on a strong creative message—designed to catch people’s attention and target those who would be interested in participating in such a trial.



○ ○ ○ ○ ○ [ CASE STUDY II ]  
**RESULTS**



30% from PriMediaPRS PRC!

FIGURE 1: Recruitment Source – Screened Subjects

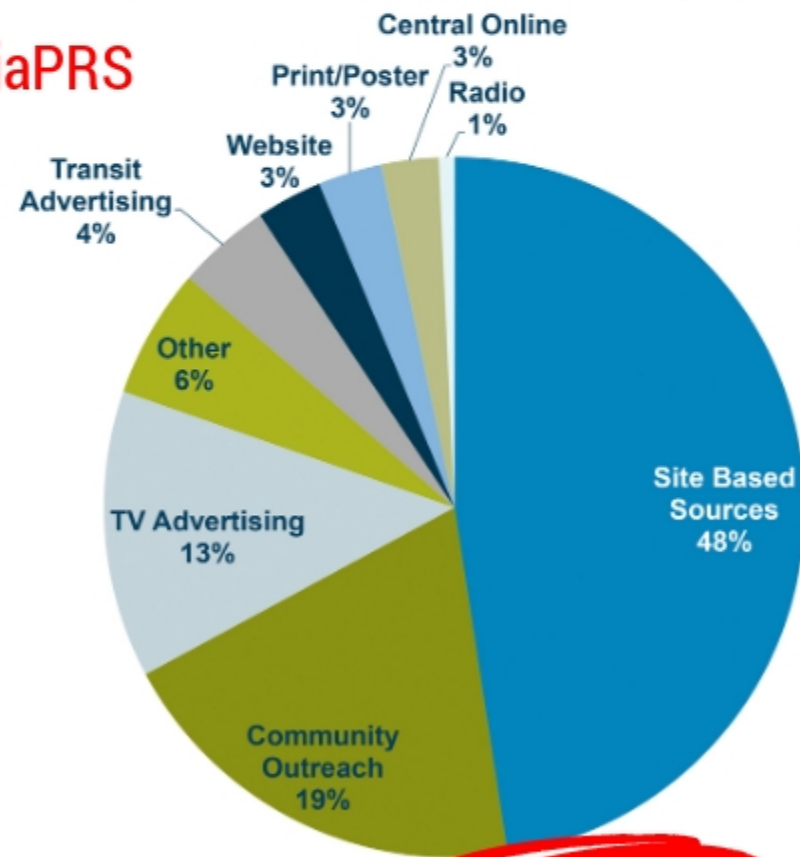


Figure 1. It is estimated that 52% of subjects screened came from the PRC efforts. As the trial progressed, site's databases became exhausted and there was a shift in recruitment strategies in order to remain on track with projections accounting for half of the recruitment by the end of the trial.

29% from PriMediaPRS PRC!

FIGURE 2: Recruitment Source – Randomized Subjects

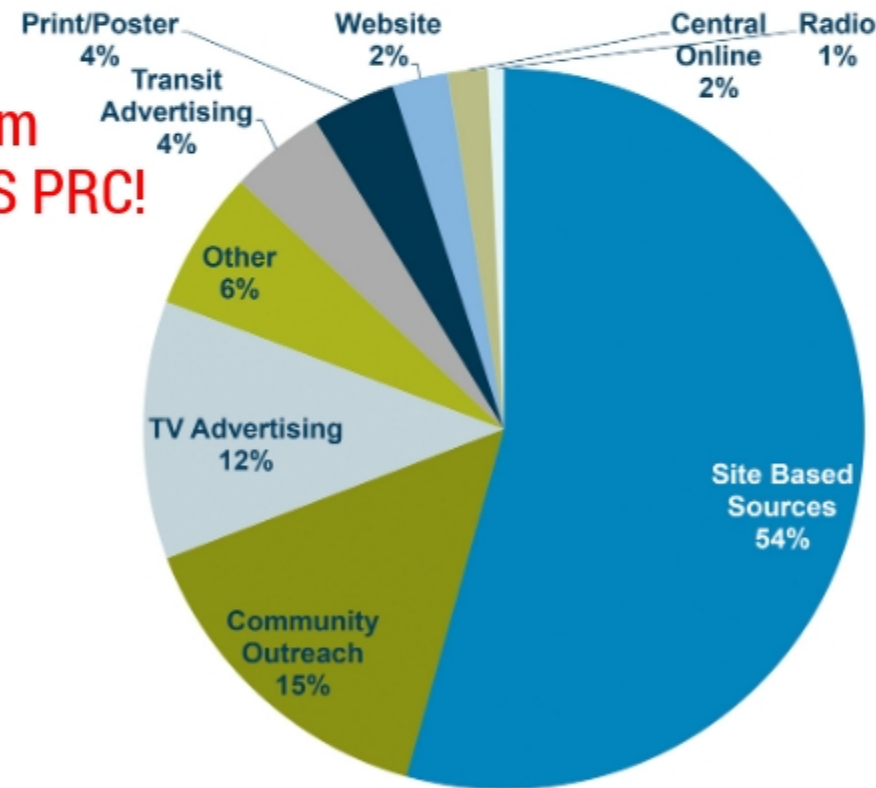


Figure 2. It is estimated that 46% of patients randomized came from the PRC efforts. The PRC efforts were essential in the Sponsor being able to meet enrollment timelines

With this trial, we were able to pull in even greater numbers...



# RESULTS

Figure 5: Actual Enrollment vs. Enrollment without the PRC

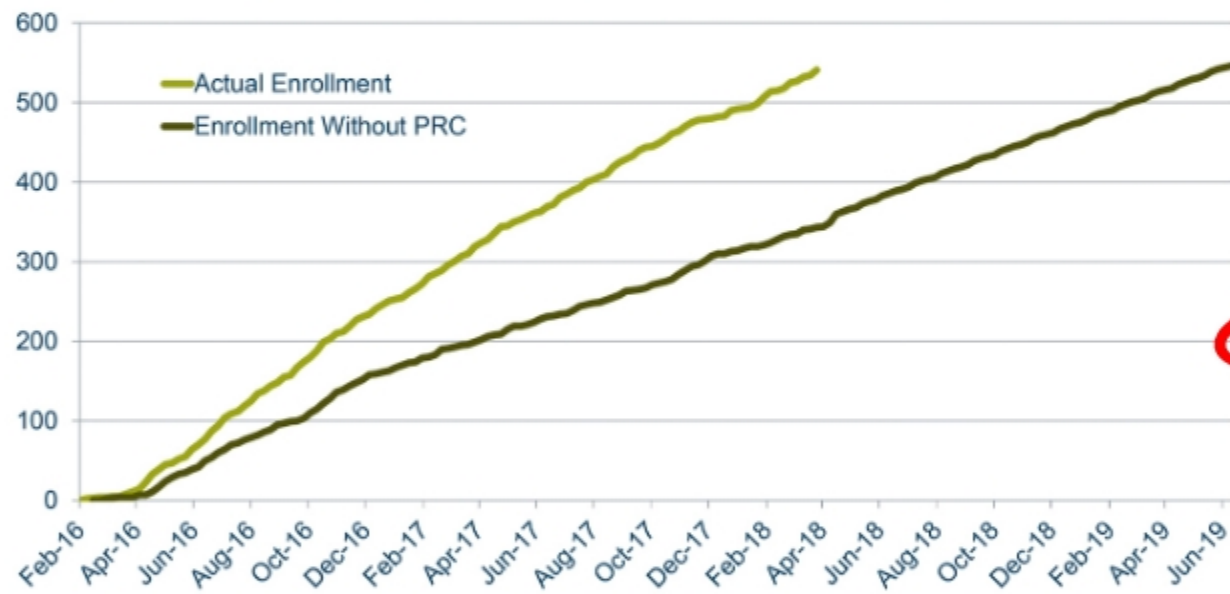


Figure 5. The duration of enrollment was 26 months with an enrollment rate of 0.46 subjects randomized per month. It is estimated it would have taken ~13 months longer to enroll the trial if PRC efforts had not been undertaken.

Without implementing a robust patient recruitment campaign, the total trial cost would have been an additional ~\$11M. This amount was calculated by multiplying operational cost of the trial per month by the number of additional months it would have taken to enroll the trial using site-based resources alone.

We like to save your time and money...

Without PriMediaPRS's PRC strategy and emphasis on early patient recruitment efforts, this trial's enrollment process would have taken around

**13 months longer to finish, costing an additional \$11M.**



# CONCLUSIONS

## Take-Home Points:

- The PRC strategies deployed in the present trial was essential in meeting the enrollment timeline. Without the PRC, the enrollment target of 540 subjects by April 2018 would not have been met.
- With site resources alone, the trial would have taken an additional 13 months to complete and an additional ~\$11M in overall trial costs. Sites were selected based on their ability to recruit patients for this study and existing database of patients.
- Site databases were exhausted approximately one year into the trial
- The PRC campaign accounted for the majority of randomizations over the final 26 months of enrollment.
- Community outreach, TV, Transit, and Social Media were the most successful tactics in the PRCs for this subject population and site locations.

The final results for this trial yield similar results to the first, proving not only the success of our PRC strategies, but the fact that those results are replicable...



**CONCLUSIONS**

**Take-Home Points:**

- The PRC strategies deployed in the present trial were essential in meeting the enrollment timeline. Without the PRC, the enrollment target of 540 subjects by April 2018 would not have been met.
- With site resources alone, the trial would have taken an additional 13 months to complete and an additional ~\$11M in overall trial costs. Sites were selected based on their ability to recruit patients for this study and existing database of patients.
- Site databases were exhausted approximately one year into the trial
- The PRC campaign accounted for the majority of randomizations over the final 26 months of enrollment.
- Community outreach, TV, Transit, and Social Media were the most successful tactics in the PRCs for this subject population and site locations.

**LIMITATIONS**

- Although every effort was made to ensure that sites were correctly reporting subject recruitment activity, activity may not be fully reported. In addition, data were collected in real-time, which may have led to reporting delays or errors in data collection.

**Alkermes**



*Why Choose Us?*





[ OUR DIFFERENCE ]

# WHY PriMediaPRS?



PriMediaPRS.com  
401.826.3600x112  
steve@primediaprs.com

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## We know how to cast the right nets!

- Unique, award winning experience (all aspects of clinical trial marketing & media).
- Best-in-class, accelerated enrollments, exceptional ROI, better quality study participants.
- In-depth Research & Software (targeting) = smart decisions.
- 35 year track record of creative excellence and documented results.
- Long-term established & successful industry relationships.
- Full-service capabilities.

Which all leads to...



[ OUR DIRECTION ]

# WHY PriMediaPRS?



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steve@primediaprs.com

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## ...More bang for your buck!

PriMediaPRS's proprietary methodology delivers the lowest rates possible on creative, production, and media, totaling between 30-50% in savings. By focusing on patient enrollment early, we get you more exposure for less money, better ROI, and significantly faster study conclusions with higher quality participants—all leading to an increase in successful trials.

**The time you could be saving means millions in additional profits.**

Simply put, PriMediaPRS's full-service capabilities give you more bang for your buck. The money you spend with us takes you farther, faster and makes a larger, clearer impact on the progress of your trial.





**PRIMEDIA** *PRS*

Patient Recruitment Solutions

On Budget. On Target. On Time.

Expertly **NAVIGATING** clinical trials  
through traditional, mobile, and digital  
media & marketing **SOLUTIONS.**

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*Thank You!*