

Case Study

Virtual Clinical Trial - 1,000 patients

How 83bar completed a 1,000-patient virtual clinical trial in 7 months at a 30% lower cost than traditional site-based recruitment.



Overview

Even before the COVID-19 pandemic suddenly appeared and emphatically nudged the entire healthcare system towards virtual delivery models, 83bar was on the cutting edge of site-less virtual clinical trial recruitment.

From August 26th, 2019 to March 30th, 2020, 83bar successfully located, educated and navigated 1,402 patients through a multi-step virtual clinical trial to evaluate an at-home colon screening test.

This campaign required patients to:

- Complete a 20-30 question pre-screening survey
- Complete a second screening process and detailed enrollment intake via telephone with an 83bar patient education specialist
- Collect then return an at-home stool sample via a provided kit
- Schedule, attend and self-finance an in-office colonoscopy procedure with a gastroenterologist of their choice
- Assist with medical records collection process

Patients were eligible for a \$100 or \$200 stipend after completing all required tasks in a defined time period.

Key inclusion & exclusion criteria

- Age 45+
- No colonoscopy in last ten years
- Average risk of colon cancer

Virtual trial recruitment pricing depends on three key variables: Total number of patients required, length of recruitment time, and how severely inclusion and exclusion criteria narrow the available patient population.

This successful campaign helped 83bar's client secure Breakthrough Device designation from the FDA and funding for a large pivotal study to begin recruitment in late 2020.

SKIP TO RESULTS

"We are so grateful that we chose 83bar to assist with our clinical trials. They've dramatically improved our ability to locate and manage a high volume of qualified patients in a short window of time. 83bar provided a streamlined, end-to-end solution to efficiently recruit patients in a highly efficient and cost-effective manner. Their demonstrated expertise at marketing, patient navigation, and logistics, coupled with their "get stuff done" sense of urgency, enabled us to reduce the timeline versus all other quotes that we received. These contributions will help us to deliver innovative technology to patients and physicians on an expedited pathway."

- Sponsor CEO

Background - Pre-Study Pilot

In spring of 2019, 83bar helped develop and conduct a smaller scale pilot to refine processes and help determine if a virtual, traditional, or hybrid approach to patient recruitment was best suited for the larger 1,000-patient study.

83bar conducted a virtual patient activation campaign while a partner vendor simultaneously conducted a traditional recruitment campaign at six separate gastroenterology offices.

The results were conclusive:

	83bar Virtual Model	Traditional Site-Based Model
Recruitment Method	Social Media + Rapid Response Contact Center	EHR Analysis and Intra-Practice Recruitment
Candidates Recruited	3,724	11
Study Completions	43	1

In the smaller scale pilot, gastroenterologists were not as committed to recruiting patients as 83bar and delivered only a tiny fraction of total candidates and study completions.

The decision: Go virtual with 83bar

Benefits of Virtual Trial Recruitment

- Less time spent contracting with vendors to procure trial sites
- Less time needed to activate trial sites
- Less resources allocated to managing relationships with trial sites
- No issues with sites deprioritizing research or prioritizing competing studies

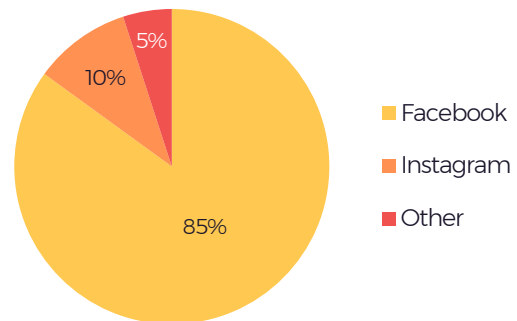
Methodology - 1,000 Patient Study

Based on learnings from the smaller pilot study, 83bar worked closely with the study sponsor and partner vendors to design an end-to-end virtual patient activation campaign using the following tactics:

Locate and screen patients via paid social media ads

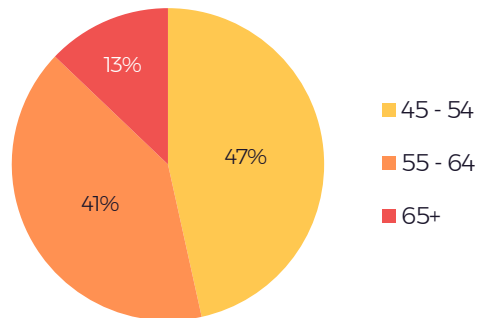
83bar located 68,075 potential patients exclusively through paid social media advertising. Ads were optimized to attract patients at the best cost, then supplemented with micro-targeted outreach to enrich demographic diversity.

Demand Generation by Source



Since 2016, 83bar has consistently generated better cost per acquisition metrics via Facebook than any other platform.

Demand Generation by Age



Yes, social media is an effective platform for generating demand from people age 65+.

Screen, educate, and support patients via a rapid response contact center

83bar patient education specialists (primarily nurses) reached out via telephone to 31,877 potential patients during the recruitment period. Nearly 2,400 total patients were then enrolled into the study.

83bar's rapid response team helped patients:

- Understand the study commitment
- Capture consent
- Navigate insurance, scheduling, stool sample collection and other participation obstacles
- Facilitate patient-facing medical records collection process

Top 3 reasons patients were disqualified from study participation

- | | |
|---|-------|
| 1. Advanced colon cancer risk due to family history | 26.4% |
| 2. Unable to self-finance colonoscopy | 21.5% |
| 3. Not enough time to provide sample prior to colonoscopy | 11.6% |

More than 11% of potential patients contacted by 83bar patient education specialists were disqualified from participation after further screening

Prepare patients to visit any gastroenterologist

Zero sites were onboarded for the campaign, meaning patients were free to choose their own provider. After their colonoscopy, patient medical records were sent from the gastroenterologist to a designated, central pathologist for review.

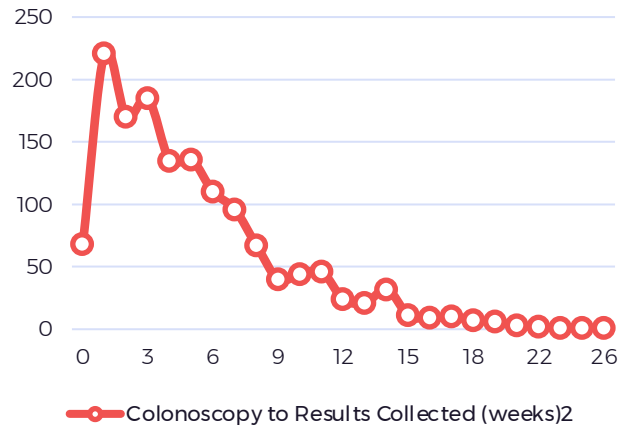
83% of potential patients did NOT have a colonoscopy previously scheduled before speaking to an 83bar patient education specialist

On average, it took 5.1 weeks after a completed colonoscopy for medical records to be transmitted to the central pathologist.

Avg Colonoscopy Completed to Records Received

5.1

Colonoscopy to Results Collected



Unsurprisingly, some provider offices were much quicker to provide medical records than others.

Build custom integrations to provide 100% visibility

With so many moving parts, it was essential that all patient activity be trackable in real time, then documented and time stamped for posterity. 83bar helped design multiple integrations, including:

- **Kit Delivery & Tracking:** 83bar triggered the delivery of stool sample collection kits then tracked all packages via a custom import of Fed-Ex data.
- **EDC Data Sync:** 83bar connected to a partner vendor to ensure all recruitment data was synced with patient and medical record data
- **Lab Portal:** 83bar developed a custom portal to help the sponsor's laboratory better prepare for daily sample processing.

Data Integrity & Security

Data integrity, security and privacy are our first priority. We comply with all pertinent safeguards to ensure proper storage and use of data.

- At-rest, in-transit encryption.
- ISO9001 and ISO27001 compliant.
- HIPAA, GDPR, CCPA, CAN-SPAM, PCI compliant.

Timeline

- **6.21.19:** Pre-campaign solutioning begins
- **7.30.19:** Final project scope completed
- **8.26.19:** Advertising launch - Pre-enrollment begins
- **10.01.19:** First kit shipped - Enrollment begins
- **01.31.20:** New recruitment paused
- **02.04.20:** 1,000th patient's medical records collected (**Recruitment Goal Accomplished**)
- **02.28.20:** Last date to allow colonoscopy procedures
- **03.31.20:** Last day to collect medical records
- **03.31.20:** 1,402nd patient's medical records collected (**Final patient to complete study**)
- **04.01.20:** Recruitment complete

A look at specific individuals and their key milestones

1st patient:

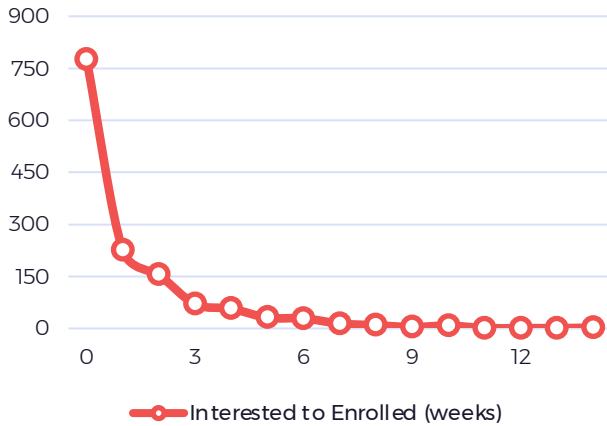
- Survey completion: 10/4
- Kit returned: 10/15
- Colonoscopy attended: 10/18
- Records returned: 10/24

It's all in the timing: How long it took, on average, for patients to complete key milestones.

Avg Interested to Enrolled

1.2

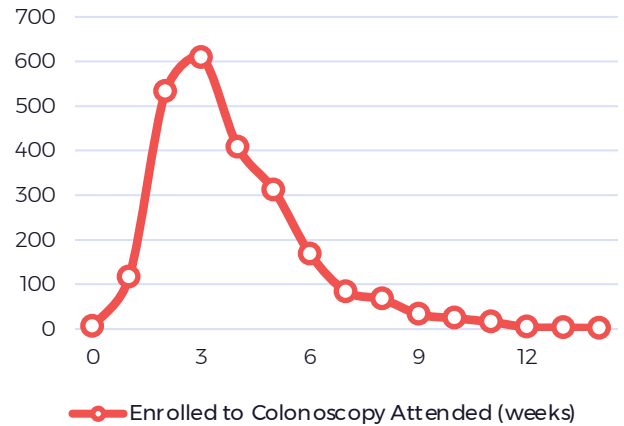
Interested to Enrolled



Avg Enrollment to Colonoscopy Returned

3.8

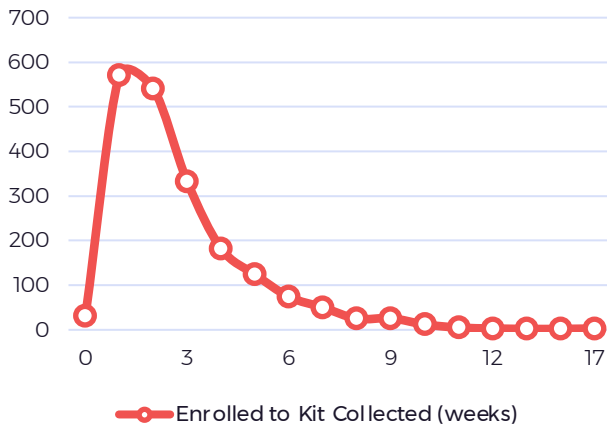
Enrollment to Colonoscopy Returned



Avg Enrollment to Kit Returned

2.8

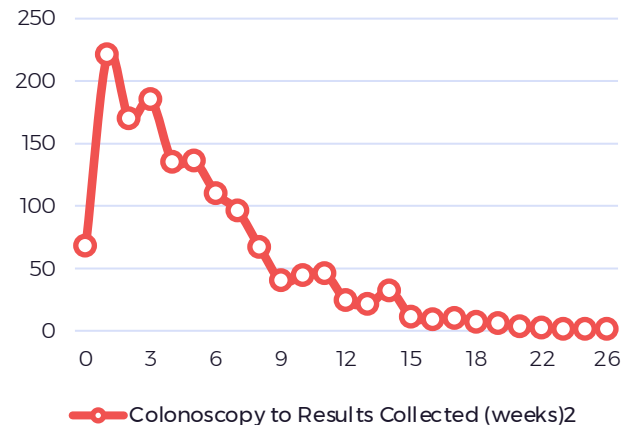
Enrollment to Kit Returned



Avg Colonoscopy Completed to Records Received

5.1

Colonoscopy to Results Collected



Results



- 2 months of development
- 5 months of active recruitment
- 2 months of closeout

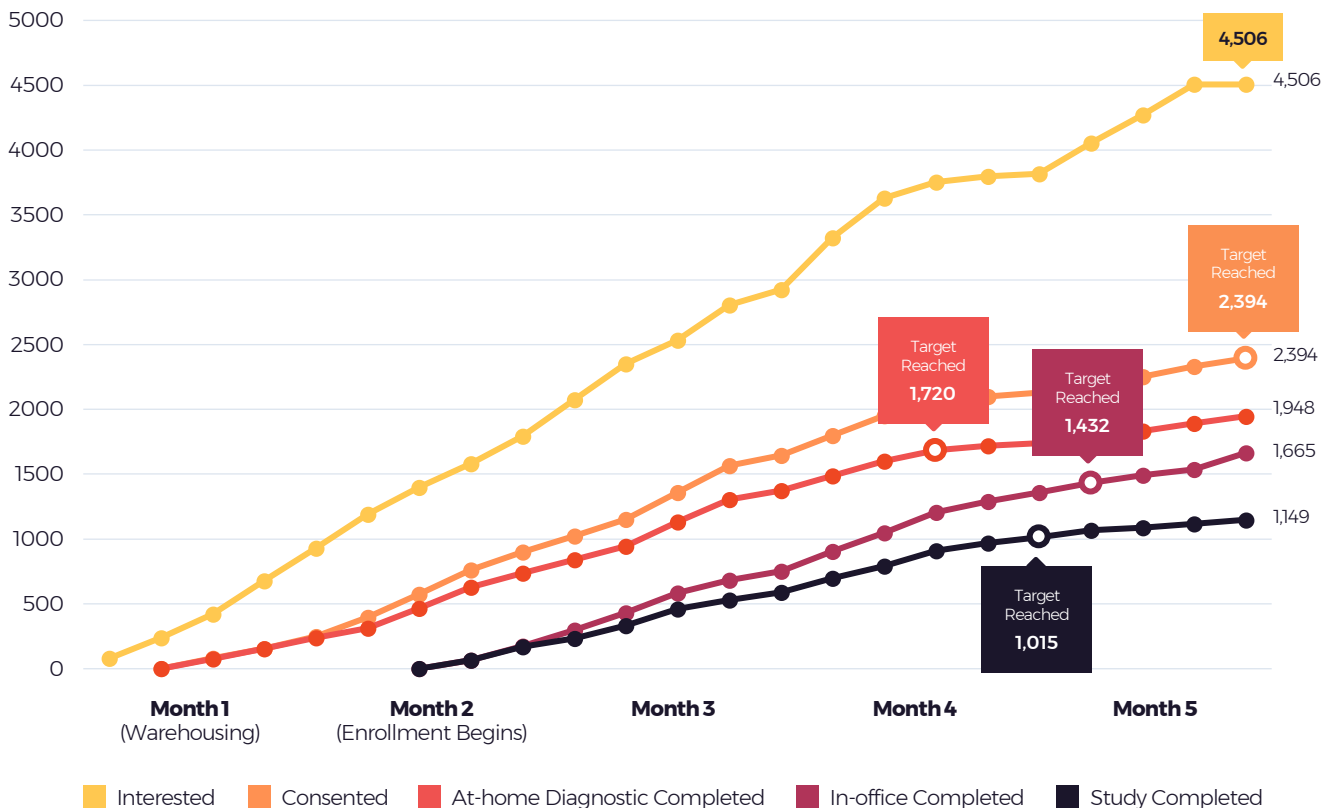


- 68,000+ potential patients recruited via paid social media
- 31,000+ patients contacted
- Nearly 2,400 patients enrolled
- Nearly 2,000 stool samples collected and returned to lab
- Nearly 1,800 colonoscopies completed
- 1,402 study completions (+40% above goal)



- Average time from online screener to study completion: **80 days**
- Median time from online screener to study completion: **72 days**
- Fastest time from online screener to study completion: **15 days**
- Slowest time from online screener to study completion: **225 days**

Decentralized Diagnostic Study Performance



Conclusion

Virtual clinical trial recruitment can be achieved in significantly less time than a traditional site-based model, often at a reduced cost. Although logistical hurdles exist, partnering with capable solution-oriented vendors can help bring your trial into the new virtual future and help you augment or replace expensive, traditional, site-based recruiting.

Author



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VP of Patient Activation

Alex is a senior marketing strategist responsible for delivering qualified patients for clinical trials, diagnostics, healthcare devices, treatments and procedures.

How can we help?

We want to help every clinical trial achieved their required outcomes. Patient health is our number 1 priority.

This case study, and many more like it, prove that our patient-centric solutions deliver results – often in less time and reduced costs.

Click below to find out more about our clinical trial solutions, plus get your FREE Pressure Test – a rapid feasibility study that offers real-time, tangible results.

[CLINICAL TRIAL SOLUTIONS](#)

About Patient Activation

83bar has developed a 4-part patient activation system integrated to:

- **LOCATE** prospective patients through risk assessment and health surveys;
- **EDUCATE** them to offer solutions and help them make informed decisions;
- **NAVIGATE** patients to action by appointment scheduling or service fulfillment; and through comprehensive follow-up; and
- **ADVOCATE** on behalf of improved treatment and health care.

Our expertise includes a wide range of medical categories:

- Aesthetics
- Cardiology
- Diabetes
- Endocrinology
- Gastroenterology
- IV therapy
- Men's health
- Molecular diagnostics
- Nutrition
- Oncology
- Ophthalmology
- Orthopedics
- Rare disease
- Surgery
- Urology / Urogynecology
- Women's health

Our Shared Success



\$1 billion+ in DTP acquisition



1,000,000+ patient prospects



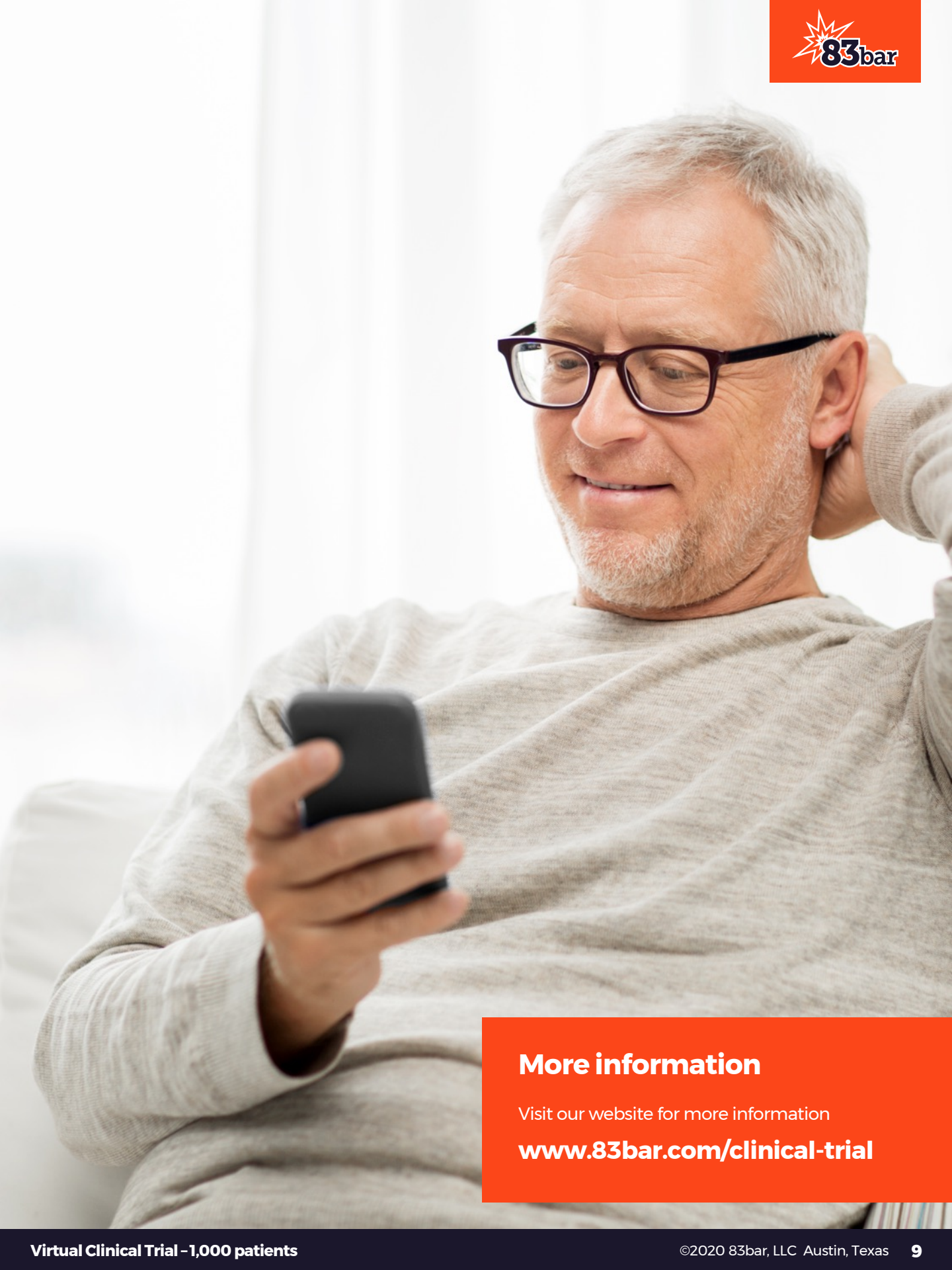
25+ partner companies



18% average Facebook conversion



>7:1 average ROI for partner companies



More information

Visit our website for more information

www.83bar.com/clinical-trial