

Research & Clinical Study

# Maintaining Patient Flow During Uncertain Times

Recruiting healthcare consumers for clinical trials in the face of business disruptors



**COVID effectively "turned off the tap" of patient referrals from healthcare providers.**



**Jan - Oct 2021: 18 natural disasters in the U.S. caused \$1B of damage each.**



**Today's healthcare consumers go online to educate themselves on treatments, ask questions, and interact on social media.**





## Business as usual is a thing of the past.

Companies in the United States and around the globe have faced serious disruptions, both positive and negative. Whether they arise from forces of nature or are forged from changing attitudes and behaviors, these disruptors are forcing companies off “the way we’ve always done it” track.

This is especially true for pharmaceutical, biopharm, medical device, diagnostics, and therapeutics companies that have so much riding on finding qualified candidates for their clinical trials.

Companies in these industries must consider new ways of maintaining business continuity in the face of disruptions to locating indicated candidates through traditional channels.

This whitepaper will discuss the following:

- ✓ Address the nature of these disruptions and provide a real-life example of how one company has overcome them
- ✓ Look at how the 83bar platform enables and accelerates new ways of doing business
- ✓ Consider projections for 2022 and beyond.



## Business Disruptors: The Bad and the Good

### COVID-19

When we consider business disruptors over the last two years, COVID-19 has been far and away the worst. From cancelled trials to lack of personnel to supply chain issues—COVID has affected nearly every aspect of business.

A particularly troubling issue has been the drop-off in patient referrals from healthcare professionals. Even before COVID, fewer patients were electing to see a primary care provider (PCP) and were going instead to urgent care.

**In fact, in a recent study of patients with healthcare insurance provided by a large, national commercial carrier, “visits to PCPs declined by 24.2% over an eight-year period, while the proportion of adults with no PCP visits in a given year rose from 38.1% to 46.4%.”<sup>1</sup>**



But COVID further reduced scheduled in-office visits. Even doctors using telehealth capabilities were often pressed for time, with little of the time they had available allotted to discussion of longer-term interventions.

At the same time, sales representatives were unable to visit doctors and other healthcare providers, further impeding the consistent flow of candidates for clinical trials. In facing the disturbances caused by pandemics, companies must find a different way to locate, qualify, and educate consumers actively searching for solutions to their healthcare issues.



## Natural Disasters

Similar to COVID-19, natural disasters such as hurricanes, tornados, floods, fires, and snowstorms have had a big impact on business continuity. Between January 1 and October 8, 2021, alone, 18 weather- or climate-related disasters occurred that resulted in losses of more than one billion dollars each in the United States.

**For the period of 1980 to 2020, the annual average is 7.1 events (CPI-adjusted), and the annual average for the most recent five years (2016-2020) is 16.2 events (CPI-adjusted).<sup>2</sup>**

With natural disasters clearly on the rise, businesses that want to achieve the goals of their clinical trials must again be prepared to find an alternative to receiving candidates for their clinical trials solely through healthcare providers.

## Changing Consumer Behavior

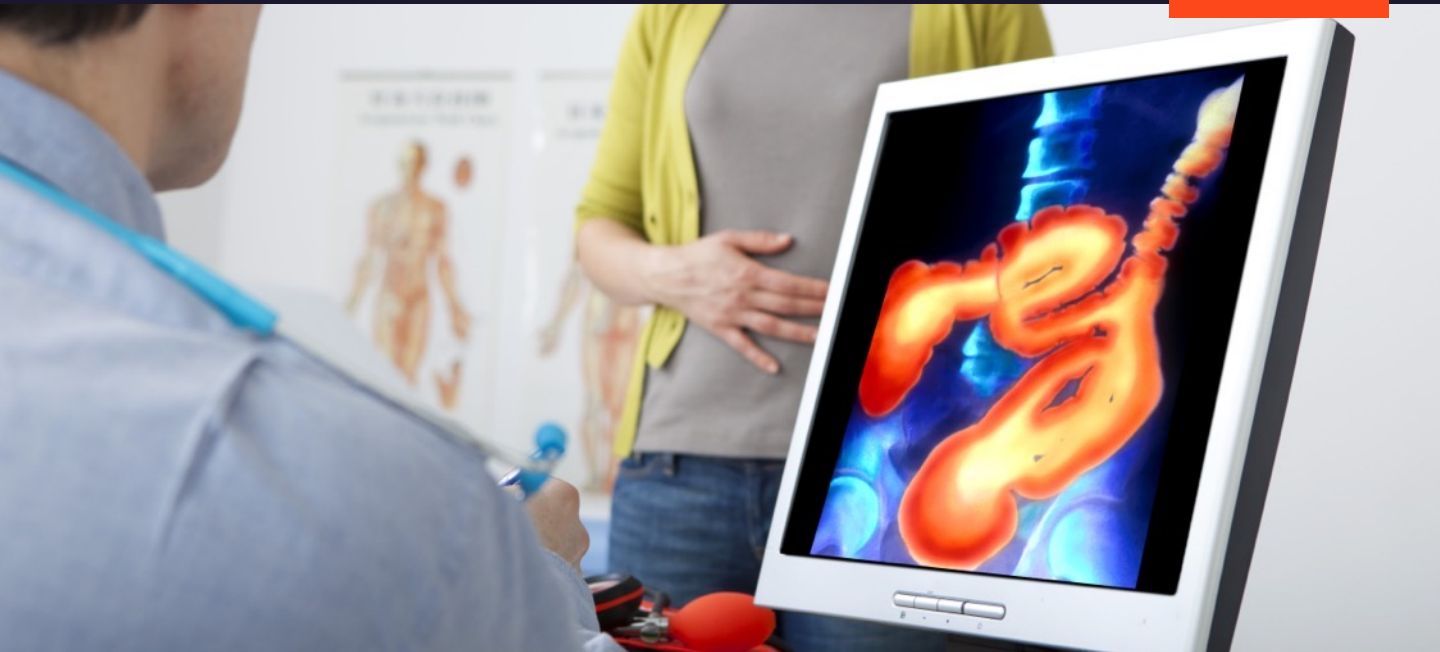
In addition to the disruptions caused by the pandemic and natural disasters, there is another disruption. Unlike the previous two, it can be turned to businesses' advantage. This is the ongoing change from passive patient to active healthcare consumer.



**According to Deloitte's recent study, 2021 Global Health Care Outlook, "Consumers are driving—and accelerating—the pace of change in health care. Their needs and goals are driving innovation in health-related products, services, and tools."<sup>3</sup>**

Healthcare consumers are becoming increasingly tech savvy. They use multiple platforms including PCs, tablets and smartphones, to educate themselves on treatments, ask questions, and engage through social media. Many have used telemedicine (especially during the pandemic) and plan to continue to do so into the future. Some consumers have even used remote monitoring technology in their homes. The bottom line? Today's healthcare consumers have transitioned from passive participants of their healthcare options, to active seekers of solutions that suit their individual needs.

These changes in consumer attitude and behavior support the idea of finding a different way to find the right candidates for clinical trials.



## Successfully Navigating Clients Around the Pitfalls

83bar is committed to helping businesses in the pharmaceutical, biotech, medical device, diagnostics, and therapeutics industries overcome the business disruptors previously discussed and maintain business continuity and clinical trial integrity. Following is an example of a client that achieved these goals with the help of 83bar's platform.

### Colon Cancer Screening

83bar began working with a diagnostics client to recruit 1,000 patients for a clinical trial to test the sensitivity of an in-home colon screening cancer screening test.

With healthcare consumers' growing acceptance of virtual models of healthcare delivery even prior to COVID-19, the client wanted to test the waters to see how consumers would respond to online recruitment versus traditional recruitment accomplished through in-office visits with healthcare providers.

83bar and a partner undertook a market feasibility test to determine which recruitment method would work best for the client. In this small pilot, 83bar conducted a virtual campaign while its partner conducted a traditional campaign. The results were overwhelmingly positive for the virtual campaign:

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

The full trial was structured as a decentralized trial for a number of reasons:

- The type of test (fecal sample) worked well for collection and submission from home.
- Candidates were attracted to the idea that most activities could be completed from the comfort of their home, leading to higher retention rates.
- A more diverse set of candidates could be obtained with less effort and cost.
- Multiple sites and site management were not required, again saving time and money, and avoiding potential issues with weather- or climate-related issues surrounding a central location or locations.

The decentralized trial followed four steps after the initial market feasibility test. **The first began** with attracting candidates with digital ads on social media, with best response rates achieved on Facebook, followed by Instagram. 83bar generated more than 68,000 leads from social media advertising. These candidates clicked through to complete a pre-screening survey.

**The second step** involved outreach to the nearly 31,900 candidates who completed the survey and met the criteria established by the client. 83bar's clinically trained patient education specialists in its Clinical Contact Center telephoned these candidates to further qualify them, explain and educate them about the study, and answer any questions. The specialists explained how to collect and return the sample and helped with insurance, scheduling, and paperwork for an in-office colonoscopy to serve as a comparison to the test and its results.

Almost 2,400 candidates enrolled as patients in the study. They then collected the samples and returned them.

**The third step** was for the patients to have their colonoscopies and obtain the results and other needed medical records to share with the client.

**Finally**, all results were analyzed by a lab and all records from the colonoscopies were collected. The initial recruitment goal was 1,000 patients, but 1,402 patients completed the study over a seven-month period.

## 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

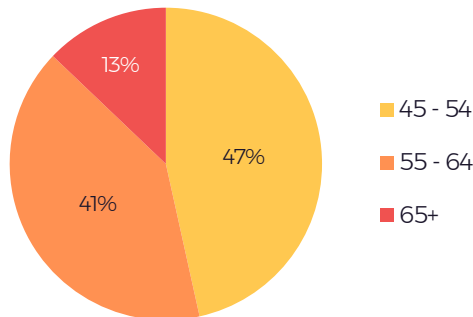
The virtual nature of this study was such that no patient's gastroenterologist was called on to function as a primary investigator. All that was needed was the patient's colonoscopy records, which enabled the study to have one "virtual" primary investigator. 83bar could then source patients throughout the United States instead of being limited to markets with participating gastroenterologists. The results? A lower cost per acquisition by expanding the pool of eligible patients as well as increased diversity because the trial was not constrained by geography. Overall, the decentralized study completed with a cost savings of 80% over the traditional model.



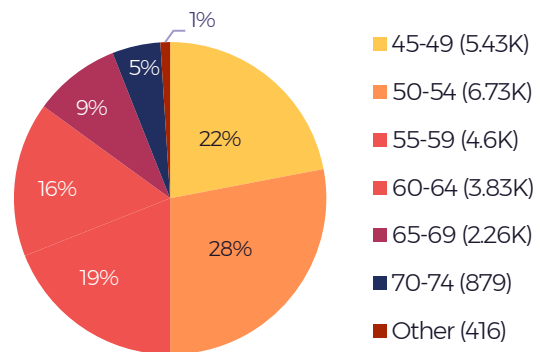
Since that study ended in 2020, the client has engaged 83bar in two additional studies:

- An analytical validation study, which requires 83bar to find patients with specific indications to ensure the patients' medical issues do not generate false positive colon cancer screening results.
- A clinical validation study, which requires 83bar to locate more than 8,500 patients that fall into specific demographic cohorts (i.e., age and ethnicity). For this study the client asked 83bar to begin lead generation before the study's lab was ready. 83bar was able to put qualified candidates into a virtual waiting room or waitlist until the lab was completed. During the time candidates were waitlisted, they received numerous communications from patient education specialists to keep them engaged and ready to continue on with the trial once the lab came online.

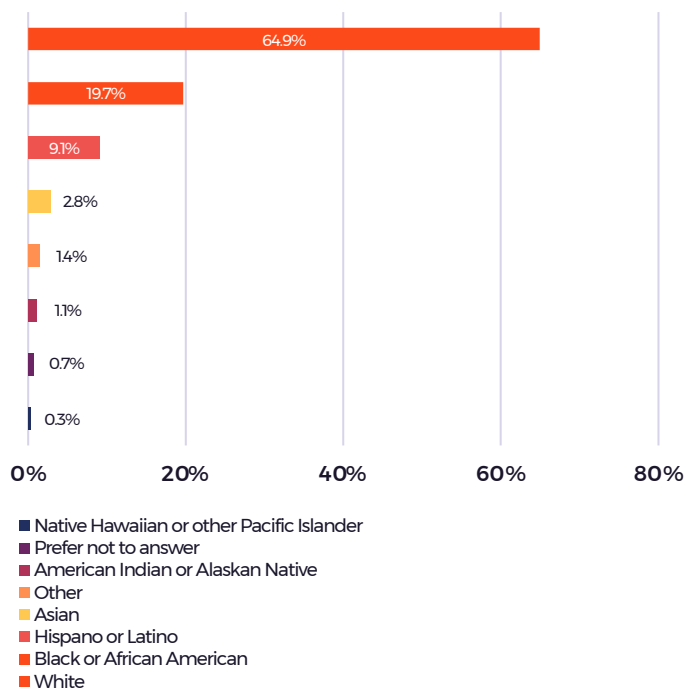
## Candidates by Age

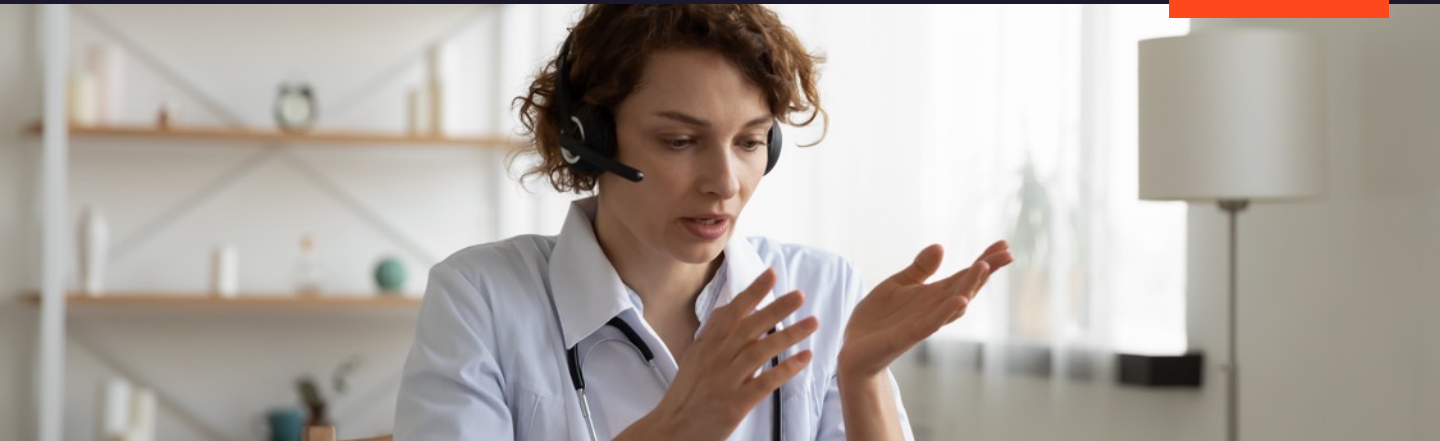


## Age Group



## Race & Ethnicity





## Applicable Disruptors

### COVID Pandemic

Although this study began before COVID-19, its virtual model, by definition, lent itself to maintaining continuity of the trial through the early stages of COVID. Patients completed most activities from their homes with the exception of the colonoscopy.

### Changing Consumer Attitudes and Behavior

With the move from passive patient to active healthcare consumer well underway and growing preference for online engagement, the 83bar platform helped the client take advantage of this disruptor in a number of ways as shown in the chart below.



#### Patient Outreach

83bar created and launched high-performing social media ad campaigns targeted to healthcare consumers actively seeking healthcare solutions online



#### Smart Screener

Candidates clicked through to an online screening tool, based on client inclusion and exclusion criteria, that enabled candidates to self-select and self-qualify



#### Clinical Contact Center

Patient education specialists contacted opt-in candidates within minutes rather than days to further qualify them, answer their questions, and educate them about the study



#### Waiting Room

Patient education specialists continued to engage by phone and email with patients who were put into a virtual waiting room because their participation in the trial was put on hold due to the delay in the lab set up



#### Patient Outcomes

83bar's platform tracked patients' progress as they moved through the patient journey by gathering data at every point along the way, including follow-up calls and emails between patient education specialists and patients





## Business Continuity Tools

### Market Feasibility Test

A market feasibility test is a limited time, usually three- to four-day, marketing campaign to understand the healthcare consumer population based on client requirements and to demonstrate 83bar's ability to address the client's issues. A market feasibility test can be used to determine if consumers are interested in virtual vs. in-office solutions. In addition, it can be used as part of a forward-looking business continuity plan to validate if 83bar can locate required patients even if a disaster hasn't happened yet or if the effects of a disaster are not yet felt.

### Waiting Room

A standard campaign, encompassing demand generation, qualifying survey/ screener, and Clinical Contact Center, is set up and launched, but instead of routing candidates to the client's normal scheduling endpoint, patients are put into a nurture flow (i.e., virtual waiting room or wait list).

### Virtual or Decentralized Trial

A virtual clinical trial moves all parts of the study online, which helps mitigate site-based issues. This option generally eliminates the need for trial sites, physical locations, and in-person communications. A decentralized trial is "more convenient, closer to the patients, or both by using a combination of virtual and physical elements to conduct the required trial procedures."<sup>4</sup>



## We can't foretell the future, but we can be prepared for the possibilities

### As COVID Lingers

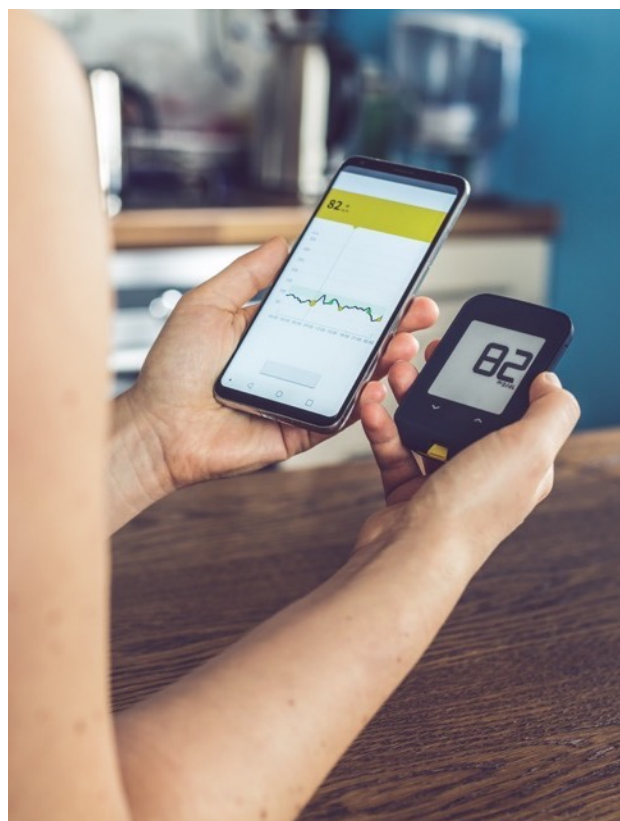
As much as we would like it to be, COVID-19 is not completely vanquished. We still face the ongoing problems of the unvaccinated and of waning immunity starting about six months after vaccination. These factors could impact re-infection rates and spur a repeat of the issues discussed in the beginning of this paper.

**At the same time, estimates are that between 15% and 80% of patients could experience long COVID four or more weeks after recovering.**

Long COVID, also known as post-COVID conditions, can appear in asymptomatic people and “can present as different types and combinations of health problems and can range in lengths of time, according to the Centers for Disease Control and Prevention (CDC).”<sup>5</sup>

These conditions can impact consumer mobility, complicate current treatment, affect scheduled surgeries, and put long-term pressure on healthcare systems. There is also a chance that COVID could mutate into a more transmissible or even more lethal virus. A mutated virus could escape immunity (natural antibodies or immunization), likely during the late fall, winter, or early spring seasons. This would result in impacts seen during previous waves of the COVID-19 virus.

Finally, we can't discount the possibility of future pandemics. We must be ready with comprehensive business continuity plans.



## The Climate in Crisis

The climate crisis is far from abating, and this means that associated natural disasters will continue to grow in strength and number. Looking at summer 2021 in the United States alone, the U.S. experienced drought, wildfires, a deadly heat wave, and then shortly thereafter Hurricanes Henri and Ida, which brought record rainfall and flooding.

**The potential for severe weather events over the winter and into the spring of next year will continue, and 2022 could see even more devastating events than in 2021.**

In addition, if potential developments with COVID overlap with the impacts of natural disasters (as they did in 2020), they could compound difficulties regarding consumer movement (and in-office visits to healthcare providers).

## Consumers Want a Say

Increased focus on, and development of, innovative at-home services and technology will further fuel “non-traditional” healthcare pathways. In addition, there is growing consumer interest in the subscription healthcare services model (as opposed to the fee-for-service model) for episodic conditions— with a view also to include some chronic conditions. With increased investment in new medical technology comes increased competition, greater choice for consumers, and a more challenging competitive market for current brands.

There is little chance that consumers will be satisfied with returning to the “good old days” of healthcare providers being the single source of healthcare information, which they impart to their passive patients. Technology has changed the equation, with the power balance sliding closer to the consumer.



## Conclusion

This paper emphasized the importance of preparing for disruptions to business operations, especially as they affect participation of indicated healthcare consumers in clinical trials.

Using a real-life client experience with the 83bar platform, the paper explored how the client was able to overcome issues during the COVID pandemic and deal with recruiting needed patients even during a delay in set up of a key component of one of its trials.

It also showed how the client turned to their advantage healthcare consumers' increasing use of online technology and the change in their expectations about guiding their own health care.

As we have noted, many unknowns continue to surround COVID-19, and weather-related disasters are only increasing. Certainly, consumers will continue to become more reliant on online and remote technologies because of their immediacy, convenience, and comfort. These are all good reasons to be prepared for the worst and be ready to achieve the best.

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