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**Whitepaper**

# The Voice of the Patient: Using Behavioral Science to Engage Clinical Trial Participants

WHITEPAPER

# The Voice of the Patient: Using Behavioral Science to Attract and Retain Clinical Trial Participants

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*Many life sciences companies are discovering the power of communicating with patients and caregivers to both recruit and retain participants in clinical trials. Rather than relying strictly on investigators to enroll and engage patients, they are proactively appealing directly to patients through various media.*

*This approach can certainly make a dramatic difference in how quickly a study is enrolled and the percentage of participants who complete a trial. But, such programs are expensive, and if not done properly, represent one more financial risk for sponsors already engaged in one of the riskiest ventures in business—bringing a new life sciences product to market.*

*So, what can improve sponsors' chances of hitting the mark with direct-to-patient outreach? The answer is the same as with every successful communication initiative: know your audience. Gathering patient insights in order to inform the messaging platform and creative strategy behind the trial recruitment and retention plan is rapidly becoming a best practice.*

## Putting Trial Recruitment into Perspective—*the Patient's Perspective*

Most observers of the life sciences industry agree that the strategies used by sponsors and Clinical Research Organizations (CROs) to recruit and retain patients for clinical trials in the life sciences are in need of an overhaul. The following statistics drawn from an Impact Report prepared by the Tufts Center for the Study of Drug Development , speak volumes:

- 37 percent of all sites in a given trial fail to meet their enrollment targets [1]
- The original timelines for Phase II-IV studies usually end up doubling in order to meet desired enrollment levels
- Only half of all patients screened complete clinical trials (although rates vary widely by therapeutic area)

1 Impact Report, Tufts Center for the Study of Drug Development, Vol. 15, No. 1, Tufts University, 2013

The good news is that the public is receptive to participating in clinical trials, at least in theory. A survey by the Center for Information & Study on Clinical Research Participation found that 87 percent of respondents were somewhat or very willing to participate in clinical research studies[2]. So, to the extent that the right patients can be reached with the right message at the right time, it should be possible to improve recruitment rates and adherence to trial forecasts.

There is, of course, no magic bullet that will resolve all of the issues surrounding patient recruitment; a range of solutions will be needed. These include more accurately forecasting enrollment targets in the first place, removing perceived barriers in the protocol itself, and adopting new media and technology platforms for patient outreach. Here, we'll offer suggestions for improving a single step in the recruitment and retention planning process: determining the most effective messages to be shared with patients and caregivers.


## *Informing vs. Communicating*

The first issue with patient outreach plans is that, in many cases, they don't exist—or they're created only as an afterthought when it appears that investigators will fall short of the mark in enrolling patient quotas. The second problem is that no matter when they're created, most patient communication plans developed today tend to gloss over the fundamentals of message development. Efforts, instead, are focused on selecting the right media and determining how best to allocate resources across them.

Very likely, this happens for a number of reasons. First, clinicians understand every aspect of the disease in question and of the proposed protocol. Thus, they inherently know what information needs to be shared with patients and caregivers and assume that the proper messaging flows directly from this. Second, the media buy is a significant line item in the study budget and so consumes a disproportionate share of the analytical and planning effort. Third, clinicians pride themselves on their scientific objectivity and strive to keep the trial process separate from the craft of advertising and marketing. So the thought of involving outside expertise to develop patient outreach campaigns is not one that study planners have traditionally entertained.

2 *The 2013 CISRP Perceptions & Insight Study: Report on General Perceptions.*

The crux of the matter is, though, that the communication challenge in capturing potential subjects' attention and then motivating them to participate in—and complete—a study is not in knowing what information needs to be presented. Rather, it is knowing what information patients need to hear, why they need to hear it, and how it needs to be conveyed in order to resonate. The difference may sound subtle, but it is not. American journalist Sydney Harris said it well, "The two words information and communication are often used interchangeably, but they signify quite different things. Information is giving out; communication is getting through."

For example, patients obviously need to know the logistics involved in getting to their clinical visit (where and when to show up). However, the emotionally relevant message may be that they will be greeted by staff members who are highly experienced working with patients just like them. This signals to them that they can expect to be understood and is likely to lead to more positive feelings about the trial and reduce their fears about trying something new.

Knowledge of what patients need to hear can be gathered by conducting primary research with a sample of target patients and caregivers. Because every protocol, every trial environment, and most importantly every patient population is somewhat unique, it is not enough to develop materials using messaging and creative templates in a cookie-cutter fashion. Each trial requires at least some degree of its own original research to gain patient insights so that the most impactful message platform and creative approach can be developed.

"Successful communication in this context hinges on having a deep understanding of what drives patient and caregiver behavior, and a whole discipline has developed around gathering patient insights and performing a behavioral analysis to inform clinical trial plans," asserts Jim Kremidas, senior vice president, Patient Recruitment, inVentiv Clinical Trial Recruitment Solutions. "Progressive companies are employing behavioral science to ensure that they approach patients in the best way to maximize their recruitment and retention rates."


## *What Behavioral Science Can Tell Is*

It should be comforting to clinical study planners that the recommended approach to message development is rooted in behavioral science—a branch of science devoted to studying the actions, reactions, and interactions of people through empirical data. It is not a matter of simply putting a creative "spin" on information.

Over the past 100 years, behavioral and social scientists have amassed empirical research pointing to the key determinants of human behavior. Using this as a guide, progressive companies are examining patient populations in a more informed manner and studying—and then interpreting—people's:

- Decision-making process. How does the target population process information and make decisions? What rational and emotional drivers are at work? What beliefs, attitudes, and past experience shape how they evaluate information?

- Motivation. What intrinsic and extrinsic factors impact whether a person turns intentions into actions? How does people's illness affect their social and emotional needs? Their values? Their quality of life? Their goals and expectations for the future?

- Social Influence. Who is likely to influence patients' decisions and ability to take action? When and how is this influence exerted?

Fictitious advertising guru Don Draper of "Mad Men" fame understood the need to understand these fundamental drivers of behavior when appealing to people, advising, "When a man walks into a room, he brings his whole life with him. He has a million reasons for being anywhere, just ask him. If you listen, he'll tell you how he got there." If Don Draper were a behavioral scientist, he would likely continue, "The key is to listen to not just what is said, but also for what is left unsaid and then interpret both from an empirical framework."

Over many decades, behavioral science professionals have developed research techniques designed to elicit this information from people. The results, when viewed in the context of the disease in question, provide direction for communicators to ensure that messages to patients and caregivers hit home.

"At the end of our research, we have a clear idea of what the 'hot buttons' are for the audience, even down to the verbiage to use in materials," explains Kathleen Starr, Ph.D. , senior vice president, Behavioral Insights and Strategy at inVentiv Health. "We can talk their language. And often, we uncover different audience segments with distinctly different messaging needs."

At a very basic level, it is important to understand how the needs of patients differ from those who support them (e.g., family members). But even among patients, it is possible that communications may need to address different tangible and emotional needs. For example, if a protocol is testing an injectable medication, patients who have not had experience with injections will have different informational needs than those who have. Plus, the emotional barriers are likely to be very different depending upon how the patients view their illness and its progression.

# The Value in Hearing the Patient's Voice

The bottom line is that gaining insight into patients' perceptions helps drive their engagement—meaning both their initial willingness to participate in a trial and their adherence to the study protocol over the long term. "Based on experience, we've seen that when patient recruitment materials really resonate with participants, enrollment rates can increase by as much as 30 percent," offers Starr.

| | | GENDER | | REGION | | | |
|---|---|---|---|---|---|---|---|
| How stressful were your research center visits during the study? | OVERALL | FEMALE | MALE | NA | SA | EU | Apac |
| Somewhat stressful | 14% | 12% | 16% | 10% | 32% | 28% | 54% |
| Very stressful | 6% | 4% | 8% | 3% | 40% | 8% | 23% |

| How well did your clinical research study meet your expectations? | OVERALL | FEMALE | MALE | NA | SA | EU | Apa |
|---|---|---|---|---|---|---|---|
| Did not meet them at all | 18% | 22% | 14% | 22% | 5% | 8% | 5% |
| Fell short of meeting them | 6% | 7% | 5% | 8% | 0% | 0% | 0% |
| Met them | 45% | 41% | 48% | 46% | 25% | 62% | 40% |
| Exceeded them | 21% | 20% | 22% | 15% | 55% | 23% | 40% |
| Greatly exceeded them | 10% | 9% | 10% | 9% | 15% | 8% | 15% |

Having a solid understanding of patient concerns and expectations can also be valuable in properly communicating what's involved in a study and setting the stage for successful completion of the trial. A study by the Center for Information & Study on Clinical Research Participation found that about a fifth of participants find the study process stressful and about a quarter report that participating in a study did not meet their expectations[3].

"To a great extent, the success of a patient recruitment and retention plan rests on positioning," explains Kremidas. "You have to reach people where they're at, and know what will trigger the right response. You may never 'walk a mile in the patient's shoes,' but using the right research techniques, you can at least try their shoes on. It's well worth the few short weeks it takes to do the research."

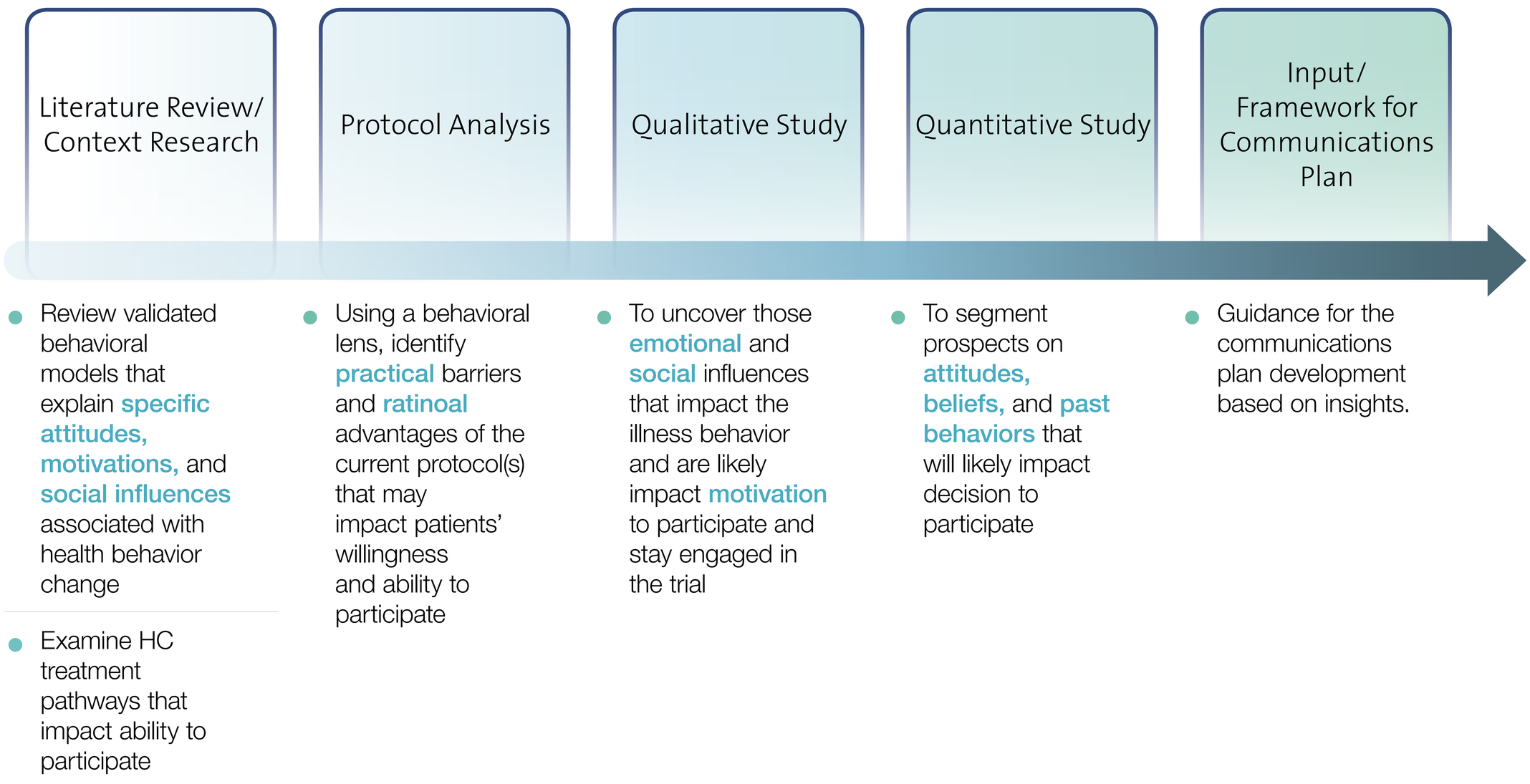
Fortunately, the insights generated for one study can be used as groundwork research to jumpstart the discovery of patient insights for other programs in the same disease area, making the investment even more cost effective. What is more, the findings can carry over into the commercial phase of the product; work done to "get to know the customer" while the molecule is still under investigation can certainly inform downstream decisions, maximizing the investment across the company.

3 *The 2013 CISRP Perceptions & Insights Study: Report on Study Participant Experiences*

## A Proven Methodology

The recommended approach involves four stages of research (See Figure 1) that can be completed in six to eight weeks. Ideally, this work is begun while the protocol is still in development and then is completed before communication materials are produced.

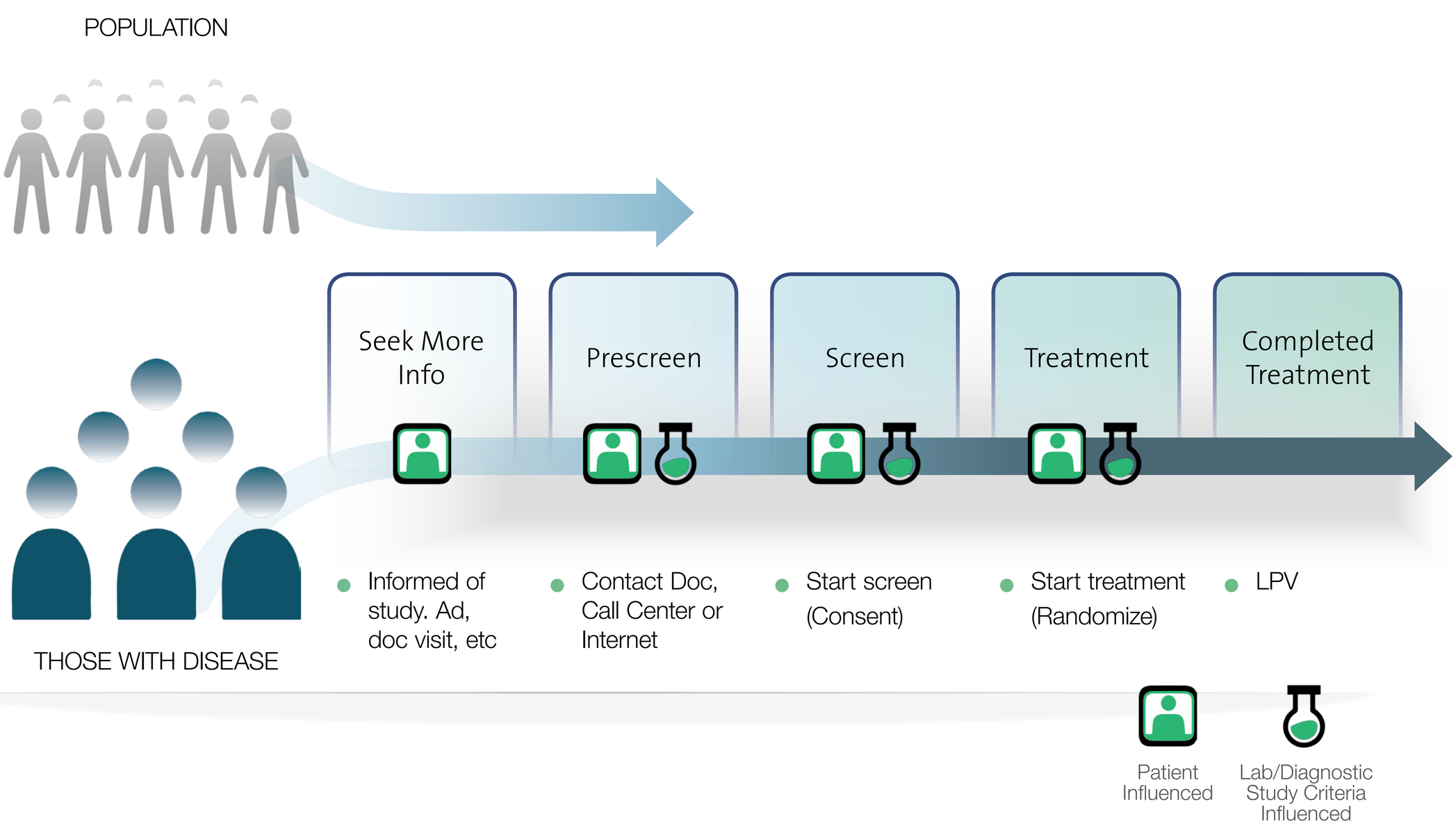
**Figure 1: Behavioral Insight Research Process**




1 Literature Review/Context Research. How does the target population process information and make decisions? What rational and emotional drivers are at work? What beliefs, attitudes, and past experience shape how they evaluate information?

2 Protocol Analysis. The draft protocol should then be studied from a behavioral lens to review precisely what people will be expected to do and to identify any factors that could impact a patient's willingness or ability to participate. This entails a step-by-step, very detailed look at each decision point the patient will face from initial awareness to signed consent (See Figure 2).

**Figure 2: Patient Decision Points**



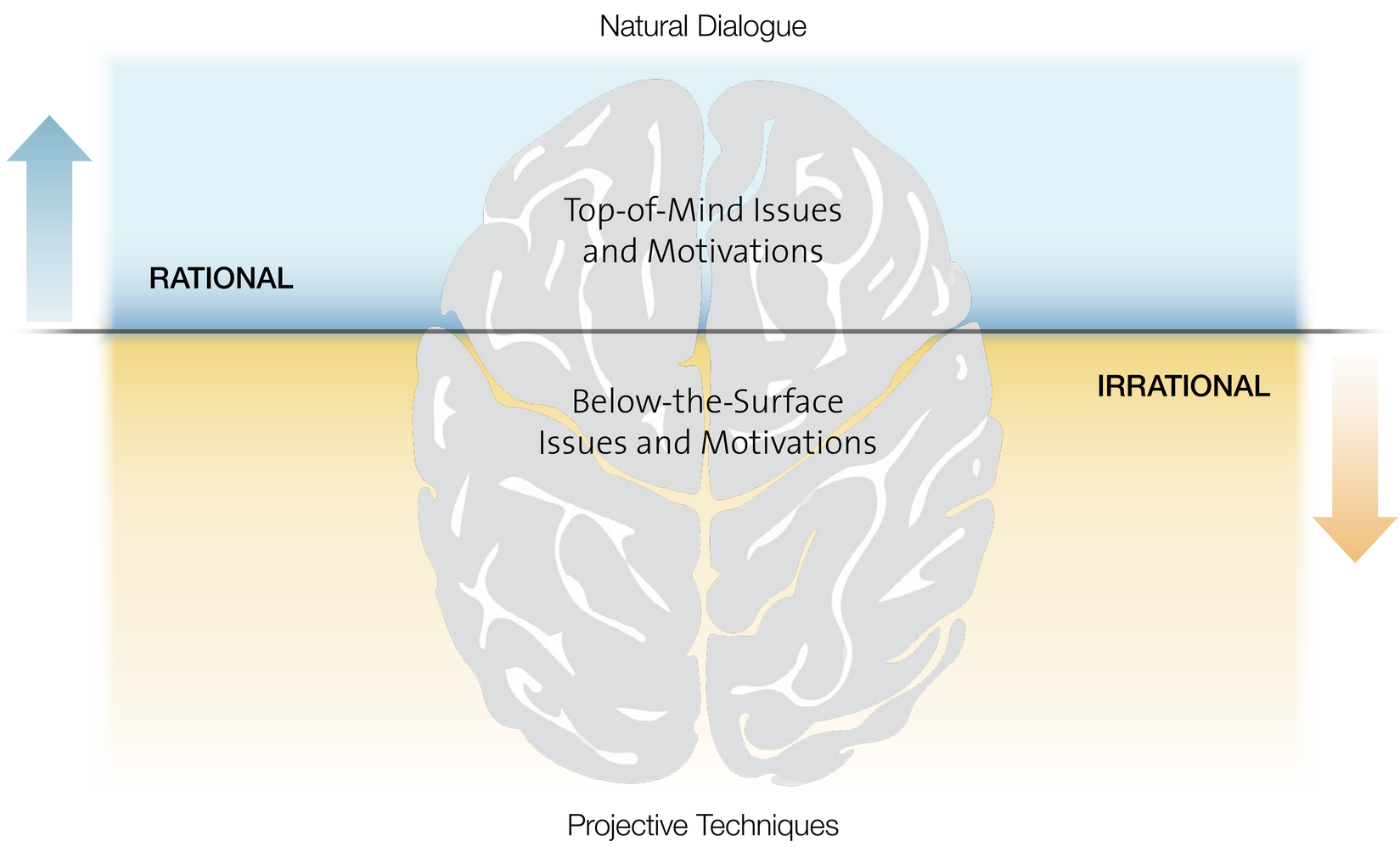

What practical barriers will the patient face? What are the rational advantages of the protocol that could influence participation? Frequently, this process reveals a procedural issue with the protocol that will be a "turnoff" for patients, possibly because it will be viewed as too inconvenient, too invasive, or too risky. When this analysis is done, the protocol can often be modified to deliver better recruitment and retention rates.

3 Qualitative Study. On the basis of the above two analyses, behavioral researchers will formulate hypotheses about what attitudes, beliefs, other influences, and situations likely impact patient behavior as they proceed from inquiring about a trial to actually completing it. They'll then design a qualitative primary research study to validate their hypotheses by listening directly to patients. This qualitative research can take the form of focus groups, dyad interviews, or one-on-one interviews, depending upon the anticipated dynamics. The study design should, of course, conform to the sponsor's budget and take into consideration the cultural differences that will likely be encountered across the scope of the clinical program.

"It's important to always keep the business need in mind at this stage," stresses Starr. "It would be easy for a researcher to get caught up in the desire to learn more because what patients have to say is so fascinating. But, this is not an academic exercise; it has a distinct business purpose, and the research effort needs to be constrained by that." Typically 10-15 interviews are sufficient for validating or expanding upon the original hypotheses.

The interviews should be designed to elicit patients' feelings on their disease and what would motivate them to participate in a clinical trial. A number of techniques exist to draw this information out of patients who may be disposed to report what they think the interviewer wants to hear or who may be unable or unwilling to respond to direct questions about their innermost thoughts and feelings. Sometimes, patients' motivations are purely subconscious, for example, and respondents are not able to articulate them directly (See Figure 3). As Peter Drucker has said, "The most important thing in communication is hearing what isn't said."

**Figure 3: Rational vs. Emotional Responses**




4 Quantitative Study. When a company is planning a number of trials requiring large sample sizes, it can make sense to invest in the final research step, which is to field a questionnaire to segment the audience based on peoples' attitudes, beliefs, and past behaviors related to the disease and likelihood of trial participation. These studies allow us to design the most relevant messages for each segment. However, the key to conducting these studies is to ensure that the segmentation is actionable. In other words, the segmentation must associate each segment's thoughts, beliefs, and attitudes with markers such as a demographic variable or a behavior (e.g., where they go for information), so that it is possible to find the segments to deliver the relevant message.

## *Informing the Recruitment Plan*

The output from the above research can be thought of as a “Patient Experience Map” in which key emotional and tangible barriers are called out and opportunities to connect with and motivate patients are identified.  These insights form the substance of a briefing document prepared for the communication professionals (often an agency specializing in direct-to-patient outreach) for conversion into a communications strategy.  This briefing document outlines the messages, tone, communication channels, and creative elements that will be most effective, by audience.

**“Don’t Try This at Home”**

*While we’ve laid out the basic steps involved in gathering behavioral insights into patients, the actual practice should not be undertaken as a do-it-yourself project. A behavioral scientist should be involved in designing the research tools and in interpreting the results, and the primary research should be conducted by either a behavioral scientist or a trained market researcher.*

*Even if an expert facilitator was given all of the right research instruments, discussion stimuli and facilitator guides, the quality of the findings would undoubtedly suffer without the expertise to connect back to what the science tells us about human behavior. At best, the conclusions drawn could be incomplete; at worst, they could be misleading. And proceeding on the basis of false information is perhaps worse than having no insight at all.*

*“What patients have to say must be decoded and synthesized,” cautions Starr. “And it takes a deep understanding of the disease state and human behavior to know which responses are outliers versus which are core and common. Those not trained in the behavioral sciences tend to be distracted by anomalies and aren’t able to discern which insights are important. Next, those insights have to inform a strategy capable of changing behavior. It is not something that anyone can just walk into the situation and do well.”*

## Guiding Principles/Best Practices

- Start early. Ideally the literature review and protocol analysis should be completed long before the protocol is finalized so that amendments can be made as needed to reflect what is learned about patient behavior. The entire research process—from the literature review through to the input to the communication strategy—takes six to eight weeks. This is a very modest time investment in order to meet recruitment timelines.

- Stay focused on the business objective. It is easy to be seduced by intriguing research angles presented by patients who are inherently interesting. And, typically with research, the answer to one question leads to still another question. You have to know how much information is enough information.

- Be flexible. Patient research should not be practiced in a cookie-cutter fashion. The methods must be modified to reflect each unique situation, be it having to do with cultural norms in a given country, the budget and timeframe allotted to the exercise, or what is already known going into the process.

## Summary

Clinical trial recruitment and retention rates can be increased through direct-to-patient communication. It is a mistake, however, to rush headlong into preparing a recruitment plan without first assessing the patient perspective. This should not be done using assumptions, but through an established body of research techniques for collecting insights into people's decision-making processes, motivational drivers, and influencers. By relying on behavioral science to guide message development, sponsors and CROs can engage prospective subjects using the most effective language, content, creative angle, and channels.

# Case Study: Strategic Recruiting for a Trial in Alzheimer's Disease

The nature of Alzheimer's Disease (AD) makes recruiting patients to participate in a clinical study unusually challenging. Patients are asymptomatic for many years, the condition is difficult to diagnose, and at some point, caregivers become the treatment decision makers. The patient journey tends to elicit complex human emotions for both patients and caregivers.

A leading pharmaceutical company planning a clinical trial of a novel treatment for AD asked for inVentiv Clinical Trial Recruitment Solutions' (iCTRS) help in devising its recruitment strategy. "Our client knew that the voice of the customer had to be woven into all communications," says Kremidas. "This called for a comprehensive media plan and messaging that was customized by audience segment across seven markets."

## Understanding the Patient Journey

The first goal was to understand what patients as well as caregivers experience as the disease progresses, starting with the pre-diagnosis stage. The inVentiv research team conducted extensive quantitative and qualitative research, including:

- **An environmental analysis** that involved auditing over 300 websites from 20 countries. Each site was scored based on the type and comprehensiveness of the information it provided.

- **A scan of social media** conversations in four languages. Using technology, we crawled 1.25 million conversations on social media and then systematically analyzed 1,600 comments.

- **Personal interviews** with more than 50 stakeholders (patient advocacy groups, neurologists, and clinical trial investigators) in seven countries. This research uncovered commonalities and differences in patient journeys by market.

Based on the findings from this research, iCTRS consultants had a solid understanding of the emotions, informational needs, and care interventions involved in the patient journey—especially those leading to trial participation.

## A Comprehensive Communication Plan

Next, inVentiv consultants developed a market-specific communication plan employing both paid media—including social media—and owned media (a company website), mapped to the patient journey. "The key was to connect people with the most relevant content, using the right emotional appeal for their market and their point in the patient journey," adds Kremidas. By taking a very strategic approach founded on patient insights, the company was able to proceed with recruitment, knowing that its communications would have maximum impact.