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Observations and Research

Inflammatory Bowel Disease Patients' Perspectives of Clinical Trials: A Global Quantitative and Qualitative Analysis

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Background: Despite recent progress, inflammatory bowel disease (IBD) therapies with pronounced long-term efficacy and improved safety are needed. IBD clinical trials face challenges with patient recruitment because of study designs, competitive or overlapping trials, and limited numbers of eligible patients. We aimed to better understand patients' awareness of, attitudes toward, and experience with IBD clinical trials.

Methods: This multinational, cross-sectional cohort study of adults with IBD recruited online consisted of 2 components: a quantitative 15-minute online survey completed by all participants and a qualitative 30-minute telephone interview completed by a subset of patients from the United States.

Results: Quantitative survey respondents (N = 226) included patients with ulcerative colitis (52%) and Crohn's disease (48%) from the United States (n = 100, 21 of whom were interviewed), Brazil (n = 26), Canada (n = 25), France (n = 25), Germany (n = 25), and Spain (n = 25); 96% of respondents reported at least a basic understanding of clinical trials. Patients rated conversations with health care providers most helpful for researching trials, but during interviews patients discussed their desire for increased patient–physician communication about trials. Major barriers to participation included invasive screening/monitoring (35% of quantitative responses) and concern over receiving placebo (35%) or suboptimal treatment (33%). Most respondents (68%) reported that clinical trial participants are "guinea pigs" for an experimental treatment.

Conclusions: Opportunities to improve participation in IBD trials include improved communication with health care providers, further patient education, and alternative trial designs. Ultimately, a better understanding of the patient perspective will be important for more informed patients and more successful recruitment and enrollment.

Lay Summary

We asked patients with inflammatory bowel disease how they felt about clinical trials. Their answers could help researchers design better trials in the future by increasing patient-doctor communication, providing education, and changing study designs to be more patient-friendly.

Key Words: patient survey, patient preference, ulcerative colitis, Crohn's disease

Introduction

Inflammatory bowel diseases (IBDs) are a group of chronic gastrointestinal diseases that dramatically impact patients' health, well-being, and overall quality of life and often require abdominal surgery.[1–3] The primary types of IBD are ulcerative colitis (UC) and Crohn's disease, two distinct conditions that share partially overlapping etiology.[4] Although pharmacologic treatment options for IBD have expanded dramatically in the past decades, currently available therapies may lose effectiveness over time and result in systemic side effects.[5–7] For example, anti-tumor necrosis factor agents have rates up to 40% for primary nonresponse and 23%–46% for secondary loss of response.[8, 9] Given the efficacy ceiling and safety concerns with existing therapies, there is an ongoing need for additional therapies to better treat IBD.

Despite the need for more effective and tolerable therapies, development has become increasingly challenging over the past decades, in part because of difficulties in recruiting patients into IBD clinical trials. Potential reasons include additional available and approved options, more complex study designs, competitive or overlapping trials, and limited numbers of eligible patients meeting necessarily strict inclusion and exclusion criteria.[10, 11] In addition, in studies that include placebo arms, investigators and patients express hesitancy and often object to participation due to lack of clinical equipoise or for fear of harm. Even patients who are interested in pursuing clinical trials often find themselves with few or no opportunities to do so,[11] due to necessary disease activity requirements, washout periods, or exclusion criteria for prior exposures. These issues relegate many trials to patients who

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have no other available therapeutic options, which is both ethically questionable and may be coercive, but even then, these same patients are often excluded due to their prior treatment history. Ultimately, these challenges in conducting IBD clinical trials delay or even prevent therapeutic advances.

Therefore, there is a pressing need for novel study designs and a change in perception of clinical trials by patients, investigators, and industry. Arguably most important is to prioritize patients' concerns in the trial design process. To this end, the US Food and Drug Administration has held (non-IBD) patient-focused drug development meetings in which patients describe living with their condition and available treatment options and has emphasized the value of engaging patients during the development process.[12]

Despite this obvious priority, there is a paucity of publications on the perspectives of patients with IBD or their first-hand experiences with clinical trials, although several recent publications have assessed patients' potential motivations for participating in and preferences regarding clinical trials.[13–15] Many publications to date have been country- or region-specific, leaving a gap in our understanding of IBD patients throughout the world.

The objective of this study was to understand awareness of clinical trials, motivations for participating, and first-hand experiences of current or previous trial participants in a global IBD patient cohort using both quantitative and qualitative assessments.

Materials and Methods

This multinational, cross-sectional cohort study consisted of both quantitative and qualitative approaches. An electronic quantitative questionnaire was developed to determine patient-specific perspectives and incentives for clinical trial participation. A targeted qualitative telephone interview was conducted in a segment of the participants to understand patient-level experiences with clinical trials.

The screening criteria, survey questionnaire, and qualitative discussion guide were developed by selected authors (L.S. and K.T.P.), with further refinement by a third-party agency (Shapiro+Raj, Chicago, IL). Quantitative data were collected using a web-based survey programmed and hosted by Shapiro+Raj (https://www.shapiroraj.com), a strategic research and insights consultancy, who recruited respondents by partnering with Schlesinger Group (https://www.schlesingergroup.com/en/), a market research recruitment firm. Schlesinger Group sourced respondents by emailing the survey link to their opt-in panel, securing referrals from respondents, and promoting the survey on their social media channels including Facebook and Twitter. Respondents were compensated for participating in the quantitative questionnaire (US$8 for US participants; US$26 for participants from Germany, Spain, or France; and US$40 for participants from Canada or Brazil) and qualitative interview (US$60, US participants only). This study was exempt from institutional review board oversight.

Participant Identification and Eligibility

Eligible participants from the United States, Canada, Brazil, Germany, France, and Spain were identified via a screening questionnaire. The screening questionnaire identified participants who met the following criteria: aged 18 to 70 years (inclusive); formally diagnosed with IBD, UC, or Crohn's disease; currently being managed by a health care professional for UC or Crohn's disease; use/had used a prescription medication for UC or Crohn's disease either currently or in the past; and not currently participating in a clinical trial sponsored by Roche/Genentech.

In order to represent the diverse IBD patient population, targeted participants included patients with mild, moderate, and severe disease activity (target maximum, 15% of sample with mild disease activity). Participant responses to screening questions were used to classify IBD disease activity as mild, moderate, or severe using the following criteria: mild, less than 3 stools per day, with little (if any) blood in the stool and little bowel urgency; moderate, 3-5 stools per day, with some blood in the stool and occasional urgency; severe, more than 5 stools per day, with regular blood in the stool and frequent urgency, inability to eat, and experiencing anemia and weight loss. Targeted participants also exhibited various degrees of clinical trial participation and awareness (target maximum, 20% of sample unaware of clinical trials). Criteria for defining participants' clinical trial participation and awareness are provided in Supplementary Figure 1.

Online Quantitative Questionnaire

Among eligible participants, a 15-minute online quantitative questionnaire was completed in the participant's native language. The questionnaire included prompts to assess the participant's feelings and attitudes towards clinical trials as well as sources of the participant's knowledge regarding clinical trials. Participants were asked to rate the importance of factors when evaluating treatment success on a scale of 1 to 7, with 1 indicating "not at all important" and 7 indicating "extremely important." As part of this questionnaire, current and previous clinical trial participants were asked to rate their satisfaction with various stages of clinical trials. Participants rated their satisfaction on a 7-point scale (from 1 to 7, where 1 indicates "not at all satisfied" and 7 indicates "extremely satisfied"). The full questionnaire is provided in Appendix S1.

Qualitative Interview

A subset of participants completing the quantitative questionnaire were selected for a 30-minute qualitative telephone interview to gather more detailed perspectives of clinical trials. Only participants from the United States were eligible for inclusion in the qualitative interview, and interviews were conducted in English only. To be considered for a qualitative interview, participants must have demonstrated knowledge of clinical trials in the quantitative questionnaire (that is, scored "aware" or "high awareness/attempted") or have been a current or past participant in a clinical trial. The discussion guide for these interviews is provided in Appendix S2.

Results

Survey Participants

Data from the online questionnaire were collected over a ~4-week period in May and June 2019. Globally, 663 respondents began the questionnaire; 226 completed it, 68 did not complete it, and 369 were disqualified because of ineligibility (Figure 1). Table 1 contains demographic information for the 226 respondents who completed the questionnaire. Participants' mean age was 41.9 years, and 62% of

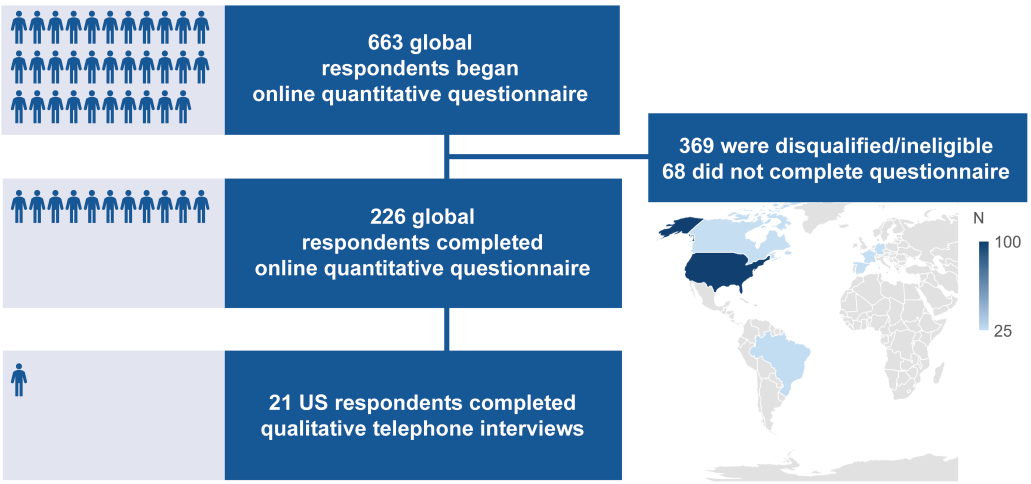

Figure 1. Inflammatory bowel disease patient survey flow diagram. Eligible participants from the United States, Canada, Brazil, Germany, France, and Spain were identified via a screening questionnaire. The blue color gradient on the map indicates the number of respondents who completed the online quantitative questionnaire in the shaded countries.

Table 1. Demographics of survey participants.

	Total	United States	Canada	Brazil	France	Germany	Spain	US interviews
n	226	100	25	26	25	25	25	21
Disease, *n* (%)								
Ulcerative colitis	117 (52)	51 (51)	15 (60)	19 (73)	12 (48)	9 (36)	11 (44)	10 (48)
Crohn's disease	109 (48)	49 (49)	10 (40)	7 (27)	13 (52)	16 (64)	14 (56)	11 (52)
Clinical trial awareness, *n* (%)								
Unaware	10 (4)	2 (2)	1 (4)	2 (8)	2 (8)	2 (8)	1 (4)	—
Aware	32 (14)	13 (13)	7 (28)	3 (12)	4 (16)	3 (12)	2 (8)	2 (10)
High awareness/attempted	150 (66)	73 (73)	16 (64)	14 (54)	13 (52)	16 (64)	18 (72)	16 (76)
Current clinical trial participant	5 (2)	—	—	1 (4)	1 (4)	1 (4)	2 (8)	1 (5)
Past clinical trial participant	29 (13)	12 (12)	1 (4)	6 (23)	5 (20)	3 (12)	2 (8)	2 (10)
Age, mean, years	41.9	42.3	48.2	32.2	43.6	45.4	39.1	—
Sex, %								
Male	38	24	44	35	52	64	56	33
Female	62	76	56	65	48	36	44	67

participants were female. Participants described their ethnic background as white (83.1%), Asian/Pacific Islander (6.5%), African American (4.5%), Native American (1.0%), Hispanic/Latino (0.5%), indigenous (0.5%), or other (4.0%); note that ethnic background was not available for participants from Germany. Seventy-two percent of participants were employed and 69% had any college degree (associate degree or above).

Roughly half (52%) of participants had UC, while 48% had Crohn's disease. A range of disease activities was reported, with 28% of participants reporting their disease activity as mild, 58% reporting moderate disease activity, and 15% reporting severe disease activity. Time from diagnosis varied, with 13% of participants having received their diagnosis of UC or Crohn's disease within the past year, 54% between 1 and 10 years ago, and 33% more than 10 years ago (Supplementary Table 1). Participants were using or had used a variety of prescription medications to manage their UC or Crohn's disease, including steroids (68%), aminosalicylates (57%), antibiotics (53%), and azathioprine (35%). Adalimumab (39%) and infliximab (32%) were the two most commonly used biologics; a full list of biologics used by patients in this study can be found in Supplementary Table 1. Fifty percent of participants previously had surgery and 18% planned to undergo surgery within the next 3 months (Supplementary Table 1). Thirty-four participants (15%) were current or past clinical trial participants. Twenty-one participants from the United States underwent the qualitative telephone interview, which took place in June 2019 (Table 1).

Clinical Trial Awareness and Education

Nearly all (96%) participants reported at least a basic understanding of clinical trials. Participants' awareness of clinical trials came from researching clinical trials on their own (48%), discussing trials with their doctors (41%), and/or knowing someone who participated in a trial (30%) (Supplementary Figure 2A); note that these responses were not mutually exclusive. The remaining 31% of participants had not researched clinical trials, discussed trials with their doctors, or known someone who participated.

In the quantitative questionnaire, patients rated conversations with health care providers the most helpful resource for researching clinical trials (Figure 2A; Supplementary Figure 2C); however, in qualitative interviews, participants stated that physicians rarely initiate conversations about clinical trials, and patients typically do not ask. Although 19/21 patients said they would feel comfortable discussing clinical trials with their physician, less than half (10/21) had done so, and some (4/11 who had not discussed trials with their health care provider) wondered why their physician had not brought them up. Patients (7/21) also felt they have little time with their physician at infrequent appointments, which are often spent running routine tests or exams.

Patients' most-used resources for researching clinical trials included conversations with health care providers (42%), pharmaceutical manufacturer websites (31%), social media (30%), online support groups (28%), and foundations, including the Crohn's & Colitis Foundation (23%) (Table 2; Supplementary Figure 2B). Participants from the United States, Canada, France, and Germany reported that health care provider conversations were the most commonly used resource (at 39%, 44%, 32%, and 68%, respectively), while Brazilian and Spanish participants' most commonly used resources were pharmaceutical manufacturer websites (50%) and social media (40%), respectively (Supplementary Figure 3). In qualitative interviews, 13/21 patients noted their preference for direct, to-the-point information about clinical trials.

Participants were presented with a series of myths (false statements) and facts (true statements) about clinical trials and asked to identify them as either true or false. While many participants correctly identified these myths and facts, there were notable exceptions (Supplementary Figure 4). The majority of participants (68%) agreed with the statement "Being in a clinical trial means you are a guinea pig for an experimental treatment" (Figure 2B) and 66% thought it was false that "Clinical trials rarely use placebo (inactive drugs) alone if an effective treatment is available" (Figure 2C). Responses to these two statements were similar regardless of current/past clinical trial participation or knowledge of clinical trials (Figure 2B/C and Supplementary Figure 5).

Clinical Trial Enrollment

Participants' primary motivators for trial participation included altruistic goals of advancing medicine, access to treatment options that could improve quality of life or would otherwise be unaffordable, potentially mitigating risks of uncontrolled IBD (such as colon cancer), and avoiding or delaying surgery (Figure 2D and Supplementary Table 2). In interviews, 9/21 patients described their desire to prevent future generations from struggling with the severe IBD they experienced in their youth (Table 2). Patients (17/21) yearned for a better quality of life and would look to clinical trials for better treatments than currently available.

Major barriers to participation included invasive screening and monitoring tests, concern over receiving placebo or suboptimal treatment, risks of the investigative treatment outweighing the potential benefits, and concerns about posttrial access to study medication (Figure 3 and Supplementary Table 3). Patients (10/21 interviewed) might be hesitant to enroll if a clinical trial requires frequent colonoscopies given the unpleasant preparation and time commitment, which may be difficult to maintain if they are working full time (Table 2). Because clinical trials can last several months, patients (13/21) worry about putting themselves at risk without their current treatment for too long. Patients (6/21) fear lengthy trials that may increase their chance of flare or multiple flares, especially if they feel somewhat controlled on their current therapy. Patients who have had surgery (3/6 interviewed) fear the risk of inducing a flare that may require another surgery they cannot physically afford.

Clinical Trial Experience

Twenty-seven percent of participants had ever pursued or attempted to enroll in a clinical trial. Of those who pursued enrollment, 80% were eligible; of those who were eligible, 69% started the clinical trial (15% of total participants). Patients who were current or past clinical trial participants were satisfied with most trial stages. The majority of participants rated the following stages positively (6 or 7 on a 7-point scale): learning about the clinical trial (62%), eligibility screening (50%), enrollment and the informed consent form (59%),

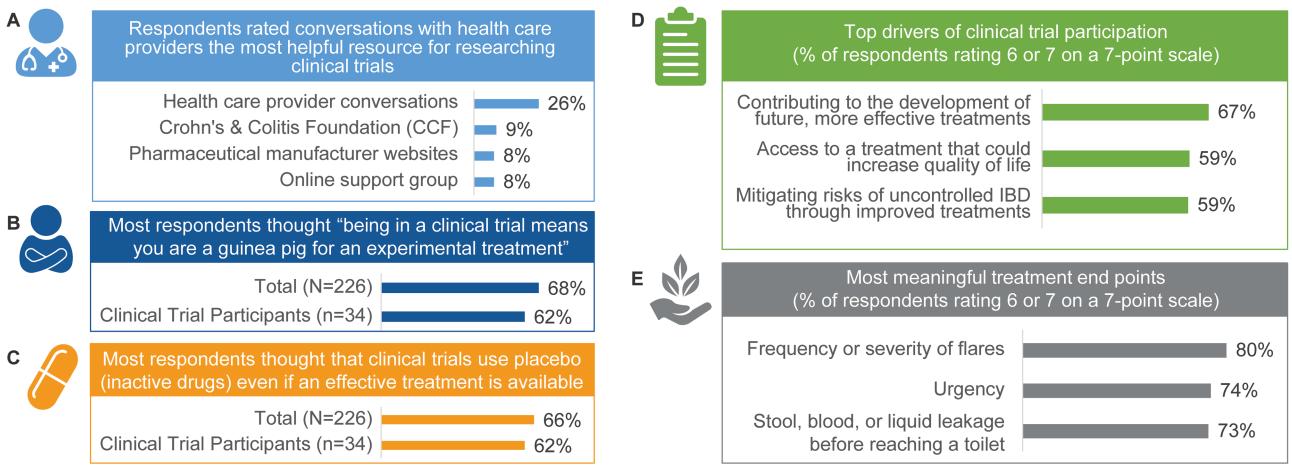

Figure 2. Summary of responses from the quantitative questionnaire. A, Top 3 most helpful resources for researching clinical trials ($N = 226$). B and C, Percentage of respondents who agreed with the indicated statements. D, Top 3 drivers of clinical trial participation ($N = 226$). E, Top 3 most meaningful treatment end points ($N = 226$). Full results for these survey questions are provided in Supplementary Figure 2C (A), Supplementary Figure 5 (B and C), Supplementary Table 2 (D), and Supplementary Figure 7 (E).

Table 2. Insights from qualitative interviews.

Theme	Subtheme	Example quotes
Resources for learning about clinical trials		"I mainly rely on my doctor. I looked at a couple of websites for ulcerative colitis before, but from what I remember they don't mention any trials, and I'm not actively looking for any trials because I am stable."—UC Patient
		"You have to really know what you're looking for to find it. People rely heavily on their physician to find these things and if the doctor isn't directly involved in studies, I think people's access is quite limited."—Crohn's Disease Patient
		"My first GI doctor recommended the Crohn's & Colitis Foundation when I was diagnosed. CCF sometimes puts us in a live chat feed. A few people I know who are in the same network, we connect and share information about clinical trials."—UC Patient
		"Mayo Clinic is a go-to because it's more of a general information site to see what pharmaceutical companies are talking about. […] As far as social media, groups on Facebook have been amazing. […] It's also a place to air frustrations like how a flare-up ruined the day. They're informational support groups."—Crohn's Disease Patient
Drivers of clinical trial participation	Improved quality of life	"I'm just looking for any help that I can get. I want to get back to the life I had prior to this disease and I don't know if that'll ever happen. It just has changed my entire life. I'm not the same person."—UC Patient
		"I'm looking for hope, someone to say, 'Yes, this might be an option for you, give it a shot.' The responses [from my gastroenterologist] have been very vague. There's not much support when it comes to clinical trials."—UC Patient
		"I've adapted to the shortcomings that I have. I travel a lot overseas with my wife, and the first thing I do is scope out the nearest hospitals and bathrooms. It's exhausting to plan that in advance. Even if a treatment could alleviate that uncertainty, that'd be huge."—Crohn's Disease Patient
	Altruism	"I really hate the thought that there are a lot of children with [Crohn's disease]. I don't know that I'll see a cure in my lifetime, but I'd like to give something back."—Crohn's Disease Patient
		"When a person opts to participate in a clinical trial it can help them, the person who is participating. But then, based on maybe the results of those clinical trials a new medication can be available or a new treatment for the next generation or for people who are just getting diagnosed. Ulcerative colitis is horrible. I'm older now, but especially younger kids. It's heartbreaking."—UC Patient
	Planning for the future	"I've had four intestinal resections; I don't have a lot of intestine left to remove. Controlling the disease and not having a fifth surgery is very important."—Crohn's Disease Patient
		"[The] two ways [I'd] get into a clinical trial is, one, if I exhausted all of my options and I needed to try something new, or two, […] for altruistic reasons. But I'm pretty well-controlled, moderately so. The only reason I'd do a trial at this point is if I reached the end of the line again."—Crohn's Disease Patient
Barriers to clinical trial participation	Concern over placebo or suboptimal treatment	"To choose to wash out my medications completely and take the risk of being on a placebo really feels like I'm jumping off a cliff."—Crohn's Disease Patient
		"I might receive a treatment that is less effective than what I am currently on or did not work for me in the past. […] I'm going in the right direction and with a trial I wouldn't know how safe and effective it might be. I had diarrhea for 8 years of my life so I don't want to go back to that."—Crohn's Disease Patient
		"There are periods when I take my current biologic and things are going well, but there are always flares. There was one [flare] that was particularly bad and we weren't sure if I'd be able to pull out of it. […] I pulled through, the biologic helped me come out of the flare and things got a little bit better […] and we didn't have to pursue secondary options."—Crohn's Disease Patient
		"I would feel more comfortable having the [active] medication so I can function in life. For my flare ups I need to be on medication or I can't leave the house. I also wonder how long the study is—is it a month or 6 months? For me to go 6 months without having a flare-up, that doesn't happen. I would be comfortable with a 3-month study."—Crohn's Disease Patient
	Invasive monitoring	"I lose a whole day of work for a colonoscopy. They usually have to put me under. And you're left groggy and sore, and the prep is awful."—UC Patient
	Logistical challenges	"My doctors have suggested [clinical trials] before, and the pluses and minuses of them. It's the journals you need to keep, a lot of time commitment on the person. I'm currently at a point that I can manage with steroids, even though it's not ideal."—Crohn's Disease Patient
		"I'm an hour outside of the nearest city, so if I'm driving in for treatment, I might have to miss work or time with family. Is it a waste of my time? Am I helping someone else or research? But if I'm not getting the real drug, I'm already failing. What if I can't start a new drug, and then what happens?"—UC Patient
Treatment end points		"Abdominal pain, flares, and vomiting are top for me. That's all quality-of-life factors. A flare encompasses all of those things."—Crohn's Disease Patient
		"The thirst and the joint pain, there are things you can do behaviorally that can help a little bit with those things, whereas the abdominal pain and the vomiting, they can feel almost beyond any sort of control."—Crohn's Disease Patient
		[With flares and urgency] you're going to have to start adjusting the stuff that you doing. You have to be mindful of going out. You have to be extra, extra careful about your diet. […] So, minimizing, mitigating the flares are critical."—Crohn's Disease Patient
Advice to trial sponsors		"Let the participants know that they will be receiving care that could be far superior to what they are getting now. Some people think, 'Oh they'll just be experimenting on me,' like you're just going to a factory or something. But in my experience…you get this team that you become familiar with and they're familiar with you. That is not, at least for me, the typical physician experience."—Crohn's Disease Patient

Note that quotes have been condensed, using [...] to indicate deletions and [] to indicate any edits for clarity.

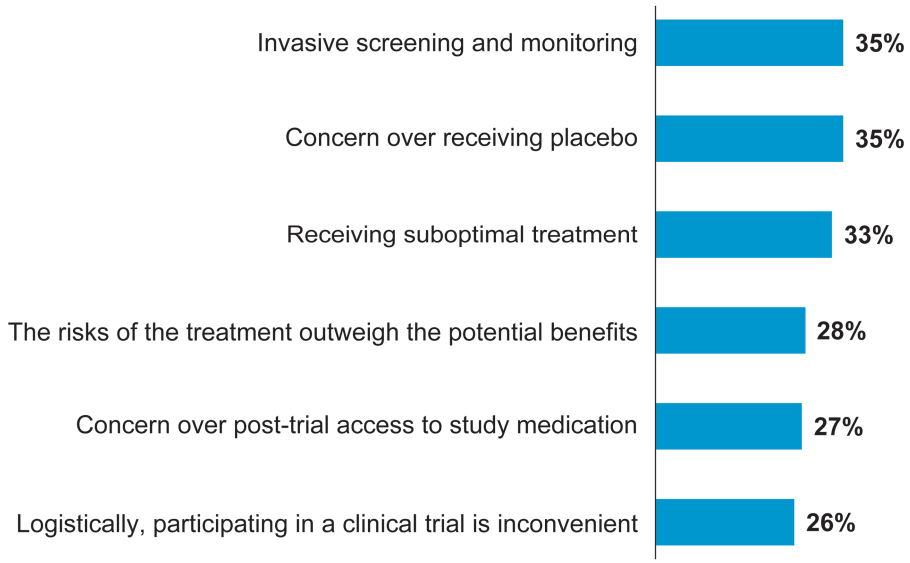

Figure 3. Top barriers to clinical trial participation ($N = 226$). Bars indicate percentage of respondents rating 6 or 7 on a 7-point scale, where 1 is "does not discourage me at all" and 7 is "discourages me very much." Full results for this survey question are provided in Supplementary Table 3.

receiving treatment (71%), treatment monitoring (62%), and trial completion (52%) (Supplementary Figure 6). However, substantial neutral responses (3 to 5 on a 7-point scale) indicate room for improvement, particularly in the eligibility screening process.

Treatment End Points

Participants were asked to rate the importance of a variety of factors when evaluating treatment success. Frequency or severity of flares was most commonly rated as meaningful (6 or 7 on a 7-point scale), followed by urgency, leakage, abdominal pain, blood in bowel movements, frequency of loose stools, mucosal healing (reduction of ulcers in the gut lining), number of bowel movements, tiredness, and weakness (Figure 2E, Table 2, and Supplementary Figure 7).

Discussion

We have described results from a global quantitative and qualitative study of perceptions and experiences with clinical trials of patients with IBD. Clinical trials in IBD have alarmingly low recruitment rates[10] that threaten progress, but remain essential given the need for additional therapies with improved long-term efficacy and safety. Our results provide a glimpse into how patients learn about clinical trials, what influences their decisions to pursue enrolling, satisfaction with each trial stage, and outcomes of treatment that matter most. With a greater understanding of these factors, we outline several recommendations to incorporate patients' perspectives into future IBD clinical trials and practice.

The key findings from our study underscore patients' desire to learn about trials from their treating physician, to improve their own disease and help fellow patients, and to participate in the discussion about IBD trials rather than feeling like a "guinea pig." Patients fear disease worsening due to receiving placebo, and do not appear to understand the rationale of such study designs, crossover options, or the potential benefit of placebo alone in many IBD studies. Current IBD trial end points include some disease characteristics important to patients but fail to properly account for many they consider most meaningful, such as urgency, leakage, and pain. Efforts are underway to improve patient-reported outcome measures for IBD trials, but these have yet to become widely adopted.[16, 17] We must establish direct lines of communication among patients, regulatory bodies, and clinical researchers to overcome the disconnect between patient-reported outcomes and objective measures of disease often used in clinical trials.

Across the countries included in this survey—the United States, Canada, Brazil, France, Germany, and Spain—patients with IBD highly value learning about clinical trials through conversations with their health care providers, emphasizing the importance of also addressing providers' understanding and approach to clinical trial enrollment. Opportunities to improve patients' clinical trial awareness include fostering communication between patients and health care providers and improving patient education about clinical trial design and ethics. These changes could be implemented as part of regularly scheduled clinic visits. The COVID-19 pandemic has also highlighted the importance of—and patients' desire for—improved patient–physician communication.[18] Working to dispel common misconceptions patients may have about clinical trials, such as those we observed in this study, could also reduce some of the barriers to enrollment. A similar approach has shown promise in a study of cancer patients.[19]

The results of this survey, particularly motivations for participating in clinical trials, are consistent with surveys of cancer patients and German and Italian patients with IBD.[13, 15, 20] Our study and other reports have identified several key barriers to enrollment in IBD clinical trials.[10, 11] First, patients want to feel like partners in their treatment, not "guinea pigs" or experimental test subjects. Second, patients are concerned over the use of placebo or suboptimal treatment. Third, patients fear the invasive screening and monitoring tests required as part of many clinical trials. Finally, patients are concerned over lack of access to study drug after the trial. A recent publication by Wood et al[14] found that IBD clinical

trial recruitment rates could be increased through altering these attributes individually, with trials becoming much more attractive to patients when multiple attributes are improved at once. These findings are all consistent with good clinical practice doctrine and the Belmont Report for ethical conduct of human subject research, emphasizing respect for persons, beneficence, and justice.[21] While current clinical trials are designed within the spirit of such an approach, the communication and understanding of it clearly needs attention based on the findings in this study.

Limitations of this study include the potential subjectivity of questions or prompts in the quantitative questionnaire and qualitative discussion guide. The patient population represented in this cohort may not be representative of patients with IBD overall; we aimed for a population in which at least 80% of participants were aware of clinical trials and most participants had moderate-to-severe disease activity. Respondents were less ethnically diverse than has been reported for populations with IBD, suggesting underrepresentation particularly of African American and Hispanic/Latino groups in the United States.[22] Nonetheless, this patient cohort provides substantial insights into aspects and attributes of clinical trials that could be improved as we develop and study new therapies or treatment strategies for IBD.

Conclusion

Changes in IBD trial design to benefit patients first and foremost would be advantageous to health care providers and trial sponsors as well. Innovative designs, such as alternatives to placebo-controlled trials, could provide better patient care while addressing major barriers to patient recruitment and enrollment.[23] Above all, though, these efforts would require and benefit from discussion and better education and communication among patients, advocacy groups, health care providers, sponsors, and regulators and could lead to a new future in IBD trials.

Supplementary Data

Supplementary data is available at *Crohn's and Colitis 360* online.

Acknowledgments

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Conflict of Interest

David T. Rubin has received grant support from AbbVie, Genentech/Roche, Janssen Pharmaceuticals, Prometheus Laboratories, Shire, and Takeda; and has served as a consultant for AbbVie, AbGenomics, Allergan, Biomica, Boehringer Ingelheim, Bristol Myers Squibb, Celgene Corp/Syneos, Check-cap, Dizal Pharmaceuticals, GalenPharma/Atlantica, Genentech/Roche, Gilead Sciences, GlaxoSmithKline Services, Ichnos Sciences, InDex Pharmaceuticals, Janssen Pharmaceuticals, Lilly, Narrow River Mgmt, Pfizer, Prometheus Laboratories, Reistone, Shire, Takeda, and Techlab. Laurent Peyrin-Biroulet reports personal fees from AbbVie, Janssen, Genentech, Ferring, Tillotts, Pharmacosmos, Celltrion, Takeda, Boehringer Ingelheim, Pfizer, Index Pharmaceuticals, Sandoz, Celgene, Biogen, Samsung Bioepis, Alma, Sterna, Nestle, Enterome, Allergan, MSD, Roche, Arena, Gilead, Hikma, Amgen, BMS, Vifor, Norgine, Mylan, Lilly, Fresenius Kabi, Oppilan Pharma, Sublimity Therapeutics, Applied Molecular Transport, OSE Immunotherapeutics, Enthera, and Theravance; grants from AbbVie, MSD, and Takeda; and stock options with CTMA. Walter Reinisch: speaker for Abbott Laboratories, AbbVie, Aesca, Aptalis, Astellas, Centocor, Celltrion, Danone Austria, Elan, Falk Pharma, Ferring, Immundiagnostik, Mitsubishi Tanabe Pharma, MSD, Otsuka, PDL, Pharmacosmos, PLS Education, Schering-Plough, Shire, Takeda, Therakos, Vifor, and Yakult; consultant for Abbott Laboratories, AbbVie, Aesca, Amgen, AM Pharma, AOP Orphan, Arena, Astellas, AstraZeneca, Avaxia, Roland Berger GmBH, Bioclinica, Biogen IDEC, Boehringer Ingelheim, Bristol Myers Squibb, Cellerix, ChemoCentryx, Celgene, Centocor, Celltrion, Covance, Danone Austria, Elan, Eli Lilly, Ernest & Young, Falk Pharma, Ferring, Galapagos, Genentech, Gilead, Grünenthal, ICON, Index Pharma, Inova, Janssen, Johnson & Johnson, Kyowa Hakko Kirin Pharma, Lipid Therapeutics, LivaNova, Mallinckrodt, Medahead, MedImmune, Millennium, Mitsubishi Tanabe Pharma, MSD, Nash Pharmaceuticals, Nestle, Nippon Kayaku, Novartis, Ocera, Otsuka, Parexel, PDL, PERI Consulting, Pharmacosmos, Philip Morris Institute, Pfizer, Procter & Gamble, Prometheus, Protagonist, Provention, Robarts Clinical Trial, Sandoz, Schering-Plough, Second Genome, Seres Therapeutics, Setpoint Medical, Sigmoid, Takeda, Therakos, TiGenix, UCB, Vifor, Zealand, Zyngenia, and 4SC; advisory board member for Abbott Laboratories, AbbVie, Aesca, Amgen, AM Pharma, Astellas, AstraZeneca, Avaxia, Biogen IDEC, Boehringer Ingelheim, Bristol Myers Squibb, Cellerix, ChemoCentryx, Celgene, Centocor, Celltrion, Danone Austria, Elan, Ferring, Galapagos, Genentech, Grünenthal, Inova, Janssen, Johnson & Johnson, Kyowa Hakko Kirin Pharma, Lipid Therapeutics, MedImmune, Millennium, Mitsubishi Tanabe Pharma, MSD, Nestle, Novartis, Ocera, Otsuka, PDL, Pharmacosmos, Pfizer, Procter & Gamble, Prometheus, Sandoz, Schering-Plough, Second Genome, Setpoint Medical, Takeda, Therakos, TiGenix, UCB, Zealand, Zyngenia, and 4SC. Swati Tole, Laura Sullivan, and KT Park are full-time employees of Genentech Inc. and shareholders in the Roche Group. Miguel Regueiro: advisor/consultant for AbbVie, Janssen, UCB, Takeda, Pfizer, Miraca Life Sciences, Amgen, Celgene, Seres, Allergan, Genentech, Gilead, Salix, Prometheus, Lilly, TARGET PharmaSolutions, and Alfasigma.

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Data Availability

Qualified researchers may request access to individual patient level data through the clinical study data request platform (https://vivli.org/). Further details on Roche's criteria for eligible studies are available here (https://vivli.org/members/ourmembers/). For further details on Roche's Global Policy on the Sharing of Clinical Information and how to request access to related clinical study documents, see here (https://www.roche.com/research_and_development/who_we_are_how_we_work/clinical_trials/our_commitment_to_data_sharing.htm).

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