

Schizophrenia[®]
& Psychosis
Action Alliance

Reimagine Schizophrenia:

Transforming How We Are Treated, Function and Thrive

Report on the Externally-Led
Patient-Focused Drug Development
Meeting on Schizophrenia

Meeting Date: November 2, 2022

Authors and Collaborators



**Schizophrenia[®]
& Psychosis**
Action Alliance



**American
Foundation
for Suicide
Prevention**



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Point of Contact

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Executive summary

Schizophrenia is a serious, disabling brain disease. While medical treatment for schizophrenia has existed for many years, these treatments are often ineffective and can cause debilitating side effects. The result: countless people with this severe brain disease are subjected to a trial-and-error approach, switching from one medicine to another in hopes of finding something that will curb what can be disabling and life-disrupting symptoms.

Many people with schizophrenia have yet to find a medicine that works for them — creating an entire population of people who cannot work or live independently and can suffer devastating symptoms of psychosis that can lead to incarceration or homelessness. Just as with heart disease, diabetes or any other serious illness, if schizophrenia isn't treated properly, it can get progressively worse.

With the goal of turning the tide and improving drug-treatment options for schizophrenia, people with the brain disease and their caregivers gathered virtually on November 2, 2022, to describe what it's like to live with this serious disease and share their experiences with available drug treatments.

Participants not only pressed drug developers to intensify efforts to develop more effective drug treatments with fewer side effects — they also urged the U.S. Food and Drug Administration (FDA) to allow broader access to the “last resort” drug clozapine, which many patients credited with restoring their ability to attend school, work and live healthy and productive lives.

The meeting, “Reimagine Schizophrenia: Transforming How We Are Treated, Function and Thrive,” was co-hosted by the Schizophrenia & Psychosis Action Alliance, the American Foundation for Suicide Prevention, Mental Health America, the National Alliance on Mental Illness and the National Council for Mental Wellbeing as part of the FDA's Externally-Led Patient-Focused Drug Development (PFDD) initiative. The FDA launched this initiative in 2012 to collect information about patient and caregiver perspectives on drug development — in particular, what people living with a disease consider to be meaningful treatment benefits and how they want to be involved in the drug development process.

Many people with schizophrenia have yet to find a medicine that works for them — creating an entire population of people who cannot work or live independently and can suffer devastating symptoms of psychosis.



KEY GOALS OF THE MEETING

- To provide people with schizophrenia and their caregivers, including members of communities of color and those struggling with homelessness or incarceration, an opportunity to share their experiences and perspectives.
- To provide the FDA and drug developers with a better understanding of the challenges of living with schizophrenia and aspects of the disease people with schizophrenia and their caregivers would most like to see drug treatments address.
- To inform FDA reviews of future schizophrenia treatments by providing insights on the treatment outcomes that matter most to people with schizophrenia and their caregivers — especially in terms of expected benefits and their willingness to tolerate specific risks. These insights can be used to improve clinical trial designs, select or create relevant measurable outcomes and update the benefit-risk framework used in regulatory decision-making.
- To begin shifting the paradigm for how schizophrenia is viewed and treated by our health system and healthcare providers, the criminal justice system, law enforcement and society.

The meeting was broadcast to the public from a dedicated website set up for the initiative; a full recording can be viewed at the following link: [Externally-Led Patient-Focused Drug Development Meeting on Schizophrenia](#)

Before the meeting, 206 people with schizophrenia and caregivers completed a detailed survey of their experiences with this serious brain disease. Data from the survey shaped the meeting content, and meeting participants were polled with similar questions during the meeting.

Several introductory presentations set the tone for the meeting. S&PAA's Board of Directors Chair shared her experience as the caregiver of a family member with schizophrenia, describing the barriers to effective treatment and the harrowing journey patients and caregivers often face when seeking proper diagnosis,

treatment and other support. Her remarks were followed by brief presentations from an FDA representative who gave an overview of patient-focused drug development and a clinical expert who provided background on the clinical nature of schizophrenia and the currently available treatments.

The core of the meeting was two live sessions with invited panelists and audience members that addressed:

1. The symptoms of schizophrenia and their effects on daily life.
2. Perspectives on current and future drug treatments.

Several key themes emerged from the pre-meeting survey and the meeting itself:

1

THE IMPACT OF SCHIZOPHRENIA IS OFTEN DEVASTATING AND CHRONICALLY DISABLING.

- Depending on the severity of their illness, people with schizophrenia may have active psychosis, negative symptoms, neurocognitive impairment and underlying neurodegenerative changes. Their behavior can be erratic and accompanied by suicidal ideation, irritability, agitation and combativeness. This is often caused by the ineffectiveness of current treatments or lack of access to treatment altogether and can result in frequent hospitalizations, legal entanglements, incarceration, homelessness and victimization in different contexts.
- Many people with schizophrenia and their caregivers expressed substantial concerns about what will happen to them or their loved ones in the future, including how the condition may impact employment, living situations, relationships with family and friends and personal safety. This is exacerbated by the presence of anosognosia (impairment of one's ability to understand and perceive their illness) in a substantial subset of individuals.

2

MULTIPLE BARRIERS STAND IN THE WAY OF SUCCESSFUL TREATMENT.

- Many people with schizophrenia never find a treatment that works for them, even after trying many different medications. This puts them at constant risk of suffering life-threatening and brain-damaging symptoms of psychosis.
- Current treatments can have such debilitating side effects — from massive weight gain to co-morbidities such as diabetes — that patients are forced to stop taking them.
- At least one treatment that does work for a significant subset of people is so heavily regulated by the FDA that many physicians won't prescribe it and many pharmacies won't stock it.

3

PEOPLE WITH SCHIZOPHRENIA AND CAREGIVERS WANT MORE EFFECTIVE TREATMENTS WITH FEWER SIDE EFFECTS — AND BROADER ACCESS TO A CURRENT TREATMENT THAT WORKS FOR MANY.

- Treatments must not only control hallucinations and delusions, but also address the negative symptoms and cognitive impairment schizophrenia can cause.
- Massive weight gain, diabetes and other severe side effects are unacceptable treatment risks.
- Severe regulatory restrictions on treatments that can be effective, such as clozapine, must be relaxed or removed to allow broader access to the medicine for those who can benefit from it — and to improve treatment equity for people with schizophrenia.
- Treatment inequity was a recurring theme — underscoring that people with schizophrenia are treated with less urgency and understanding than those with other types of severe diseases.
- Participants called for improved awareness and less stigma among healthcare providers, law enforcement and the public that schizophrenia is a neurodevelopmental brain disease — and that treatment delays and interruptions can cause irreparable cognitive damage and worsening psychosis.
- Anosognosia — a common symptom that prevents people with schizophrenia from understanding they have the disease — directly affects people's ability to seek and receive care. Yet many people with the disease, their families and even healthcare providers are not familiar with this dangerous symptom.

Introduction

Patient-focused drug development is a systematic way of gathering patient perspectives and input on their medical condition and how it is treated. On November 2, 2022, people with schizophrenia and their caregivers convened for a virtual Externally-Led Patient-Focused Drug Development (EL-PFDD) meeting to share with FDA staff and drug developers their perspectives on living with the serious brain disease and what they need from current and future medications.

Roughly one-third of patients with schizophrenia have “positive” symptoms that are resistant to drug treatment.



PRE-MEETING SURVEY

Before the meeting, a survey was distributed to gain greater understanding of the experience of living with schizophrenia and what those with schizophrenia and their caregivers want from drug treatments. The survey, commissioned by S&PAA and the meeting co-hosts, informed the meeting content and helped identify meeting panel participants. It was designed by Faegre Drinker Consulting with input from people with schizophrenia and caregivers and consisted of a combination of multiple choice, ranking and open-ended questions. The initial invitation to complete the survey was sent on August 9; the survey period ended on September 26.

Survey participants were adults who had been diagnosed with schizophrenia for at least six months and caregivers of adults who were diagnosed but could not complete the survey on their own. Professional/paid caregivers were excluded. Participants were required to be U.S. residents who had reached the age of majority. They represented the broad spectrum of those living with schizophrenia and a wide range of diverse perspectives.

Participants were recruited through outreach to the membership email lists and social media platforms of the meeting co-hosts. The symptoms of schizophrenia and the discrimination people with the disease experience made some hesitant to participate; others avoided using their full names. Although hesitancy to self-identify as being affected by schizophrenia may have presented a barrier to participation, the extent to which this barrier affected participation is unknown.

Table 1 provides a detailed breakdown of the demographics and employment and educational status of the 206 survey participants.

Participant Characteristics	Self-Completed (n=78)	Caregiver-Completed (n=128)
Age in Years (range)	45 (21–80)	38 (18–81)
Male Sex (%)	47.4	77.3
Race (%)		
American Indian or Alaska Native	1	1
Asian	10	2
Black or African American	3	4
White	76	87
Multiple races	10	4
Another identity or prefer not to answer	0	2
Ethnicity (%)		
Hispanic, Latino or of Spanish origin	8	7
Employment Status (%)		
Employed full time	22	4
Employed part time	22	9
Actively looking for work	6	2
Not employed	31	84
Retired	15	1
Prefer not to say	4	0
Educational Status (%)		
In school full time	4	4
In school part time	13	7
Not in school	83	88
Don't know	0	1

The survey assessed four key areas of schizophrenia burden:

1. Severity of symptoms
2. Effects of symptoms on daily life
3. Medications used to treat symptoms
4. Reasons for medication cessation and switching

Results of relevant aspects of the survey are described in the following sections.

MEETING FORMAT AND DESIRED OUTCOMES

The five-hour meeting was webcast to maximize participation of all stakeholders. It was designed to provide first-hand insights to the FDA and drug developers about the challenges and treatment needs of those living with schizophrenia, to help ensure that what matters to people living with the disease is prioritized in the drug development and FDA review processes.

An important goal was to provide a voice to people in hard-to-reach populations, such as those who have struggled with homelessness or incarceration, and to ensure equitable representation of communities of color. Another goal was to begin changing how people with schizophrenia are viewed and treated by the healthcare system, the criminal justice system, law enforcement and society.

Tim Franson, M.D., a principal at Faegre Drinker Consulting, moderated the meeting with co-moderator Paulie Benjamin, an advocate for people with schizophrenia and a person living with the brain disease.

An important goal was to provide a voice to people in hard-to-reach populations, such as those who have struggled with homelessness or incarceration, and to ensure equitable representation of communities of color.

The meeting opened with the following introductory presentations:

S&PAA Board Chair Mary Palafox, R.N., described the challenges faced by people with schizophrenia, emphasizing that those affected by this severe neurological condition deserve the same rights, entitlements and standards of care as people with any other neurological condition.

Bernard Fischer, M.D., deputy director of the FDA's Office of Neuroscience — Division of Psychiatry, gave an overview of the PFDD initiative and its role in developing new medicines for psychiatric diseases.

Matcheri Keshavan, M.D., Stanley Cobb Professor of Psychiatry at Harvard Medical School and a practicing psychiatrist in the Department of Psychiatry at Beth Israel Deaconess Medical Center, presented the overview of schizophrenia symptoms and treatment approaches that follows below.

Terry Frangiosa, M.B.A., a member of the S&PAA Board of Directors, provided a top-line summary of pre-meeting survey results at the end of the meeting.

The rest of the meeting was divided into two sessions:

1. The symptoms of schizophrenia and their impact on daily life
2. Current and future treatment approaches

Each session included a panel of pre-recorded testimonials from people affected by schizophrenia, a series of live polling questions and a moderated discussion, during which remote participants could call in or email questions.

DEFINITION, IMPACT AND SYMPTOMS OF SCHIZOPHRENIA

Schizophrenia is a chronic neurodevelopmental brain disease that typically becomes pronounced during adolescence or early adulthood and lasts over one's lifetime. It affects about 2.6 million people in the United States, resulting in an estimated annual cost to society of \$281.6 billion and an unquantifiable amount of suffering for affected individuals and their families. Schizophrenia is one of the most disabling medical conditions; for example, fewer than 20% of those with the brain disease are able to maintain paid employment.

Schizophrenia shortens a person's lifespan by 20–25 years due to an increased risk of suicide, cardiovascular disease, substance use (especially smoking), metabolic syndrome, obesity and accidental death. Many of these conditions actually result from treatment with antipsychotic medicine.¹

The diagnostic criteria for schizophrenia include what's known as "positive" symptoms, such as disordered thinking, disrupted problem-solving, hallucinations, delusions and disorganized behavior, as well as "negative" symptoms, such as poor motivation and sociability, a reduced ability to experience pleasure or other emotions and lack of awareness of the illness itself, a symptom called anosognosia.¹



Although currently available treatments for schizophrenia may counteract many of its "positive" symptoms, they do little (if anything) to address "negative" symptoms or the cognitive impairment that can result when schizophrenia is inadequately treated and allowed to progress. These medications are not effective in many patients with schizophrenia and their side effects can make them very difficult to tolerate.¹

Dr. Keshavan noted that all antipsychotic agents are roughly similarly effective in treating the symptoms of schizophrenia, adding that clozapine may be more effective than other medicines for people whose schizophrenia symptoms have proven resistant to treatment with other drugs.

Newer, second-generation antipsychotics, also called atypical antipsychotics, pose a lower risk of movement disorders as a side effect than older, first-generation antipsychotics. However, some second-generation antipsychotics (such as clozapine and olanzapine) can have substantial metabolic side effects, including weight gain and diabetes.²

Roughly one-third of patients with schizophrenia have "positive" symptoms that are resistant to drug treatment, according to Dr. Keshavan. This issue — combined with the side effects of these medicines — contributes to more than three-fourths of patients stopping treatment within two years.²

¹ Jauhar S, Johnstone M, McKenna PJ. Schizophrenia. *Lancet*. 2022 Jan 29;399(10323):473–486. doi: 10.1016/S0140-6736(21)01730-X. PMID: 35093231.

² Goff DC. The pharmacologic treatment of schizophrenia—2021. *JAMA*. 2021 Jan 12;325(2):175–176. doi: 10.1001/jama.2020.19048. PMID: 33369626.

Meeting Topic 1: The symptoms of schizophrenia and their impact on daily life

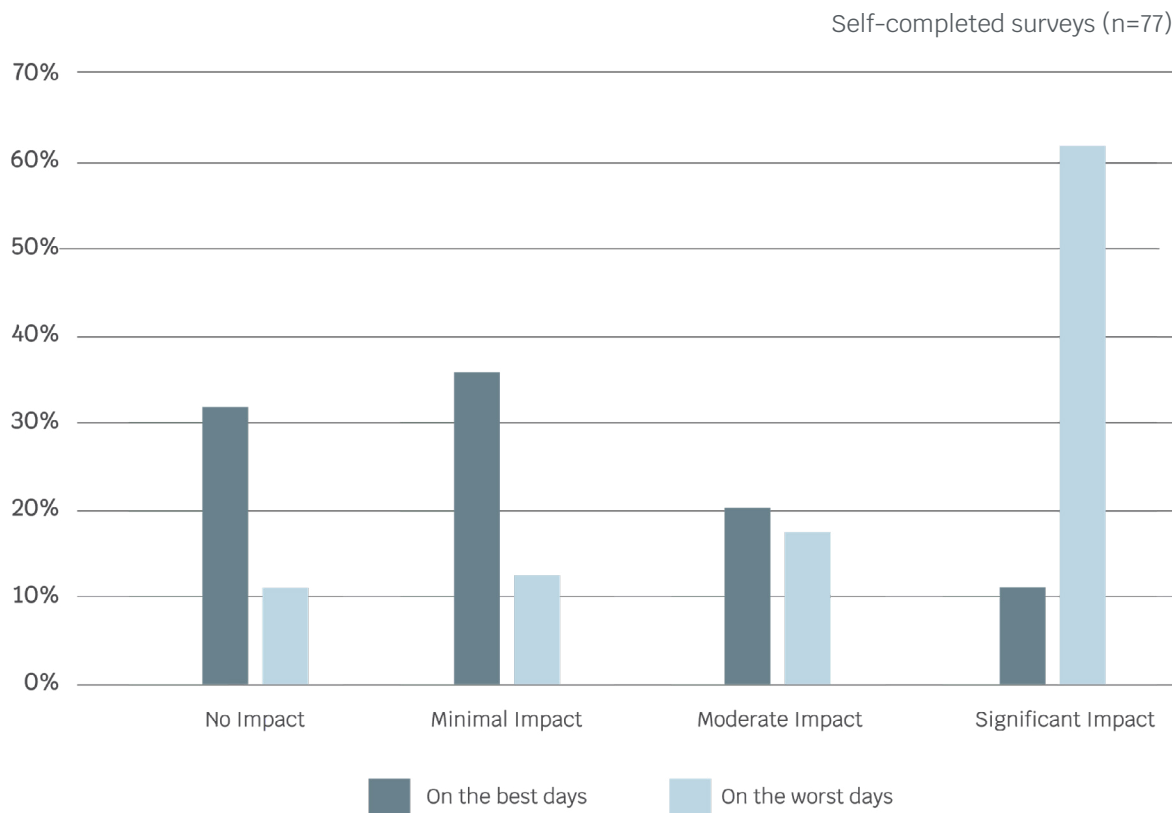
Participants in both the survey and the meeting described the significant, often disabling burdens created by schizophrenia and its symptoms.

Despite current treatment, symptoms are frequent and life impacts are significant

People with schizophrenia who completed the survey themselves reported experiencing milder symptoms,

with 37.7% reporting moderate to severe symptoms in the last 30 days, while schizophrenia caregivers reported severe symptoms in those they cared for. Over 70% of caregivers expressed “substantially significant difficulty” for their loved ones in 11 of 14 categories. At least 60% of those who completed the survey themselves reported experiencing at least a mild impact from 14 of 15 symptoms on their ability to function and live the way they would like (Figure 1).

FIGURE 1. Survey participant responses to “How much do your schizophrenia symptoms negatively impact your life...?”



In addition, between 40% and 50% of those who completed the survey themselves reported a significant impact on their ability to function in daily life from lack of energy, loss of interest in social activities, believing something that others don't believe, loss of motivation and not trusting other people. More than two-thirds of caregivers reported significant difficulty for their loved ones in all but one of those areas.

Those who completed the survey themselves also reported having significant difficulty in the last six months with many activities of life — primarily with working, starting and finishing things and remembering things. Figure 3 provides more details. Again, caregivers reported more severe effects, with more than 70% reporting that the person they cared for had significant difficulty with 11 of the 14 items listed in Figure 3.

Figure 2 provides more details about how symptoms of schizophrenia affected the ability to function for participants in the self-completer group.

FIGURE 2. Survey participant responses to “Have any of the following diminished your ability to function and live the way you would like?”

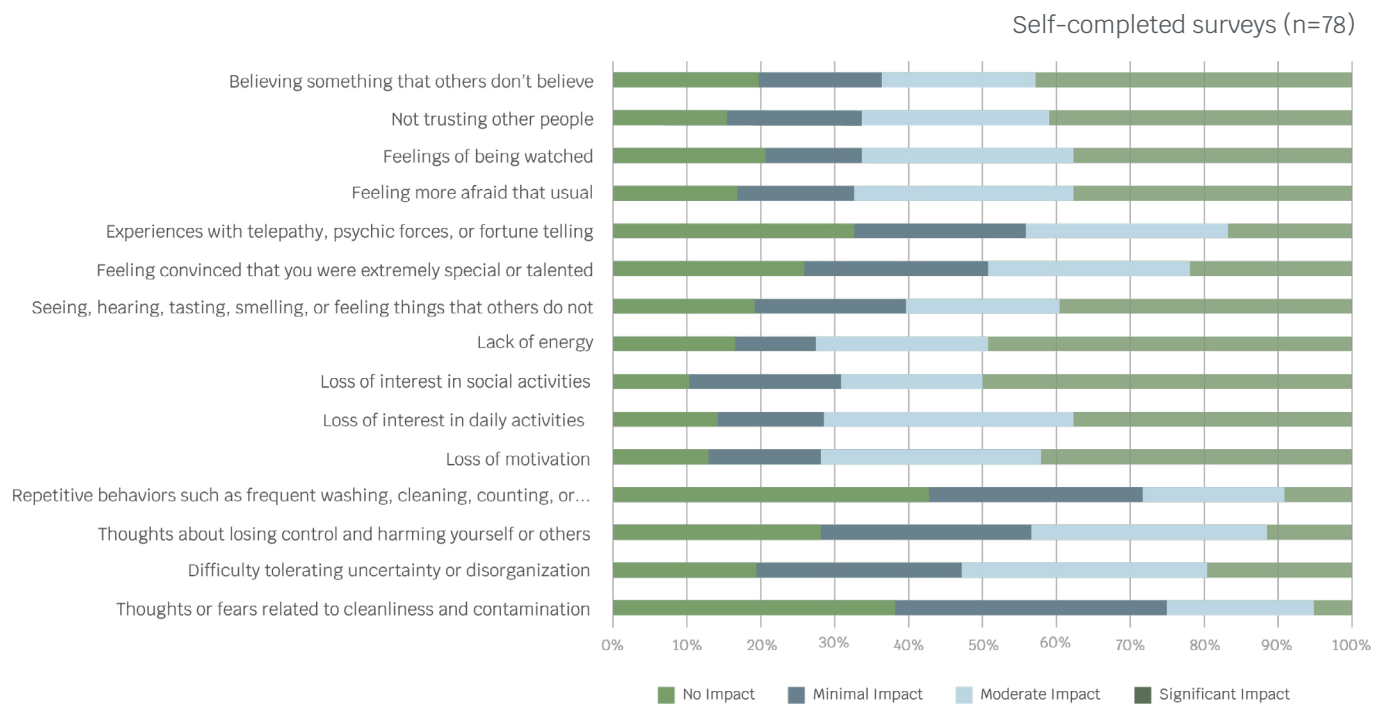
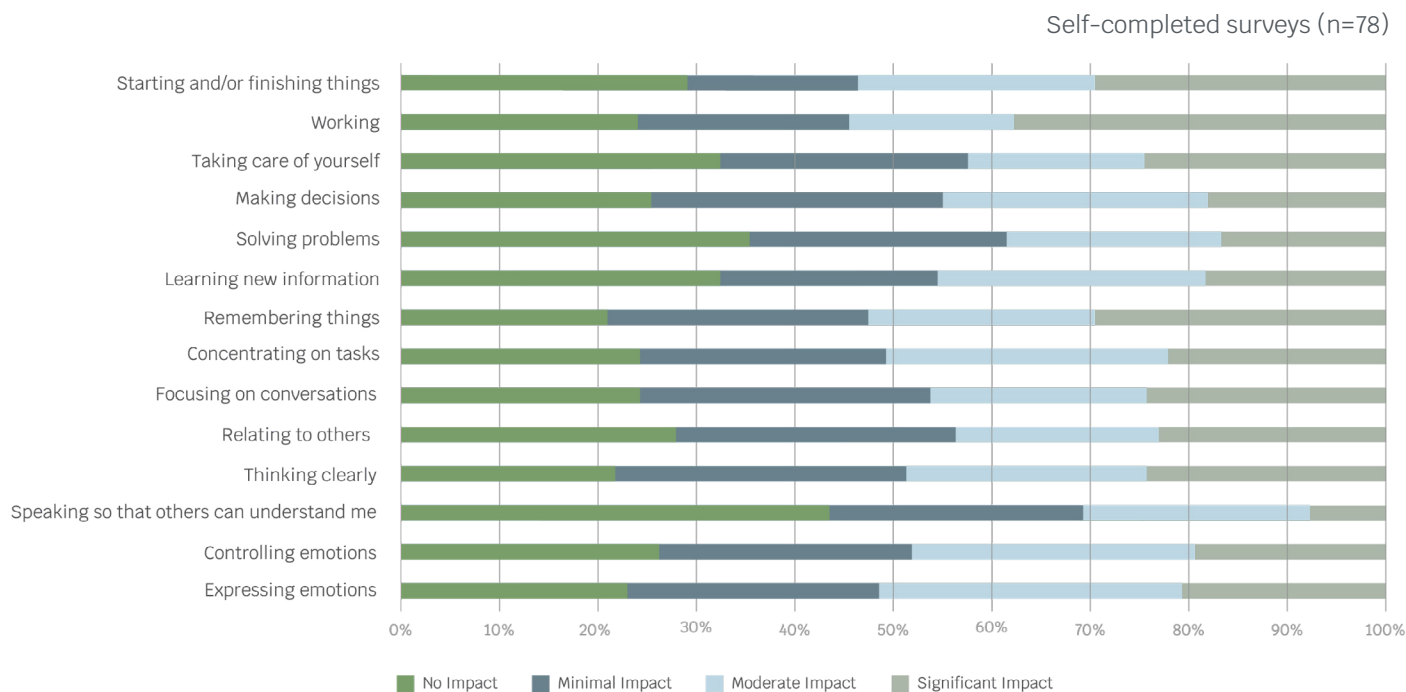
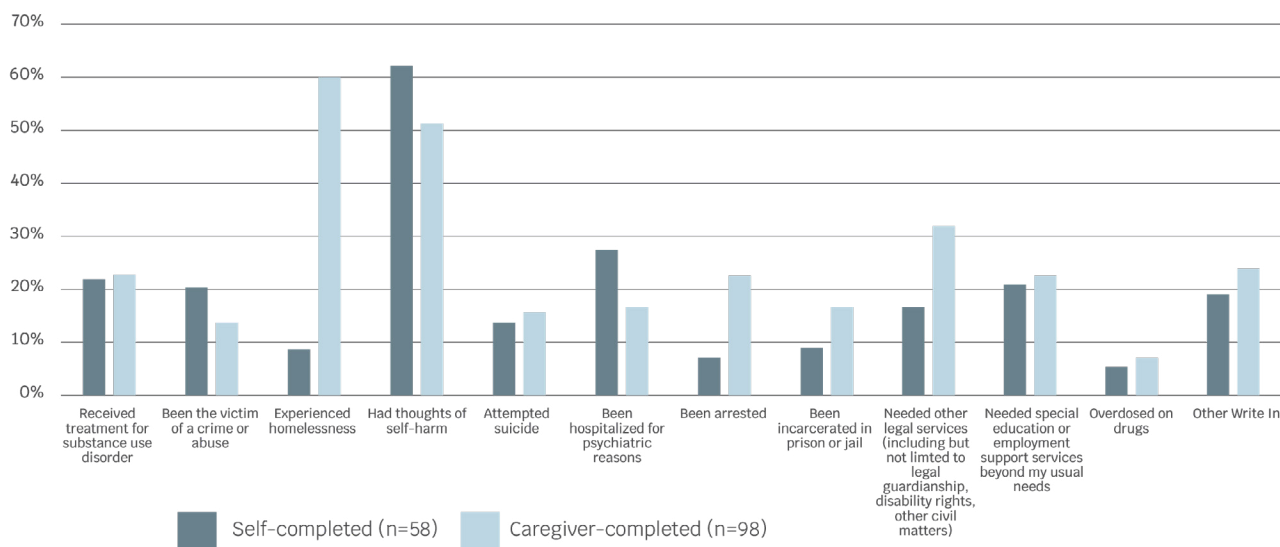


FIGURE 3. Survey participant responses to “In the past six months, have you had difficulty with any of the following?”



More than half of all survey participants reported that they (as a person with the disease) or the person they cared for had thoughts of self-harm and nearly 60% of caregivers reported that the person they cared for had periods of homelessness in the last year. Figure 4 provides more details on these and other negative experiences.

FIGURE 4. Survey participant responses to “In the past 12 months, have you done or experienced any of the following?”



Like survey participants, panel members and those who submitted call-in or written comments at the meeting reported a range of schizophrenia symptoms that caused significant negative impact, including the inability to live independently, substance use disorders and broken relationships.³



Some days I'm a high-functioning multitasker who can operate on multiple levels ... then three days later, I have mush brain and cannot express or explain a thing and cannot remember anything... It's a struggle just to get a thought out of my mouth or to focus on the task at hand."



Cognitive dysfunction causes daily life disruption

Schizophrenia can cause significant cognitive dysfunction — which can become progressively worse over time, especially if the disease is not treated properly. Meeting participants described how this brain deterioration compounded their difficulties with work, school or even just the activities of daily life.

An Asian woman from Texas who spoke on the panel described how cognitive impairment caused by schizoaffective disorder made it hard to think clearly, learn new information and remember it. As she put it, *"I need academic accommodations in graduate school now. I didn't need those as an undergraduate or before I got sick. I need more time to think on tests, so I have extended testing times. And in daily life, I always forget where my phone is."*

She added, *"I worry a lot about getting dementia because I'm afraid the cognitive impairment is going to get worse over time and when I'm older, I won't be able to take care of myself as well as I can now... I can take care of myself pretty well on my best days, but on the worst days, I need to be hospitalized for suicidal ideation or just paranoia."*

A woman from Tennessee submitted the following written comment: *"Some days I'm a high-functioning multitasker who can operate on multiple levels, and I can unlock my true personal best and achieve the highest of standards. Then three days later, I have mush brain and cannot express or explain a thing and cannot remember anything. I have word salad. It's a struggle just to get a thought out of my mouth or to focus on the task at hand."*

A Northern California mother of a son who had schizoaffective disorder for more than 20 years — and died in a hospital psychiatric ward — reported that *"in the last few months of his life, he lost his ability to remember things. He couldn't function at work. He had loss of motivation and problems trusting people, and his delusions came back."*

Delusions and hallucinations can lead to violent urges

Some panelists reported delusional thinking or auditory hallucinations that urged them to commit violent acts against family members.

A White man in his 60s recounted that when he was in his mid-20s in 1979, delusional thoughts led him to kill his wife and severely injure his infant son; he was acquitted in court by reason of insanity and committed to a psychiatric institution. *“I took chlorpromazine for a while when I was at Trenton Psychiatric Hospital. The doctor took me off it to see how I would react without medication. I did very well for many years, from 1979 to 2000, [but] in May 2000, I had a relapse. Since my most recent release from the hospital in 2004, when I was put back on meds, I have had no problems.... The worst things that happened are the actions that took place in 1979. The memories remain with me. They never go away. People don’t understand what it is to live with the memories. What worries me most about having schizophrenia is having a relapse that puts me back into the hospital for years to come. My life will be over.”*



It’s devastating that you can’t get help for an individual until they become a criminal.”

A middle-aged White woman said her symptoms began after the birth of her daughter in 1993.

“I began hearing voices telling me to harm her and myself... I was concerned that I would end up hurting my child, and I was afraid to tell anyone about the voices because they might take my child from me... I decided

to go to my primary-care physician. He listened and referred me to a psychiatrist.”

After a long wait to see a psychiatrist, she was admitted to a hospital psychiatric unit and prescribed medication, but she continued to hear voices and had thoughts of suicide. She then received electroconvulsive shock therapy, which worked temporarily, but the voices soon returned. As a result, she had to give up her teaching career.

“Throughout the years, I had to be hospitalized many times, and at times of stress, I struggled with voices and hallucinations.” She began using food to self-medicate. *“The more stress I was under, the more food I would eat... It did not help that the medications I was on listed gaining weight as a top side effect.... As my illness increased, so did my weight. In 2018, I hit my highest weight of 400 pounds. I felt horrible.”*

Anosognosia can block treatment, leave caregivers feeling powerless

Anosognosia — one of the most common and most dangerous schizophrenia symptoms, given that it prevents many people with the disease from being treated — was described as a major obstacle to proper treatment and support.

“Anosognosia has had the biggest impact on my son’s schizoaffective/bipolar disorder. He has no insight into his fixed delusions,” a California woman said in written comments. *“He will not take meds or see his doctor or partake in any counseling.”*

A woman living in New York described her son’s struggle with schizoaffective disorder: *“His older sister has schizoaffective disorder. He began to develop symptoms similar to hers over the last three or four years and refused to acknowledge that there was anything wrong. It would come and go, but as of about a year and a half ago, he became unable to work. He couldn’t function, but he would not go and get checked out because he couldn’t believe that he had the same illness as his sister. He had delusions, he had paranoia, he had visual and auditory hallucinations, became convinced that we weren’t his parents, that he was the son of a rich individual and was supporting the entire United States with his trust fund.”*

After her son's functioning improved, he moved to another state and got a job, but then sustained a head injury and relapsed. *"He became threatening, and he began to send us emails and texts that were frightening. I actually got a court order in this distant state to get him taken in for a 72-hour evaluation. But the state police decided when they talked with him that he didn't quite meet their criteria, and they got the judge to cancel that order. A month later, he was arrested at the airport with guns, and he's been incarcerated ever since. It took 11 months for him to even get a full psych eval. He's currently being evaluated and hopefully, we'll get some treatment. It's devastating that you can't get help for an individual until they become a criminal."*

A White man from Washington state who is living with schizophrenia and who spoke on the panel wrote that his therapist's approach helped him break through his



[Anosognosia] led to jail, prison, homelessness... when his symptoms are actively present, he's unable to hold any type of job, manage finances, keep up with appointments."



anosognosia. *"What probably helped me gain the most insight on my illness was actually having a psychiatrist who was able to explain the condition very well to me... I think that if there were more explanation of the biological basis, that would make it easier for people to accept that they have a mental health condition... How we communicate with each other as patients and professionals is very crucial to the process of giving somebody insight on whether or not they have a condition."*

A woman from Virginia submitted a written comment saying her loved one's anosognosia prevents him from taking his prescribed treatment — allowing his schizophrenia to control his behavior. "He's adamant that the hallucinations and delusions are real, not symptoms of a disease. Many of the psychotic medications have worked to reduce the hallucinations and delusions, but the belief of not being ill remains, and he quickly stops taking the prescription."

Schizophrenia symptoms can trigger alcohol, drug use

A middle-aged, White, non-binary individual reported that after they entered college, paranoia in their 20s forced them to move back in with their parents. After treatment with medication and psychotherapy, they were able to start a family. However, when they stopped taking their medication because they assumed it was no longer needed, they began self-medicating with alcohol, and their marriage fell apart. *"Eventually, I got divorced and almost lost everything."*

A middle-aged Black woman described her experience caring for a son who has been living with schizophrenia and substance use disorder for 22 years. At age 18, he began his career as a medical specialist in the U.S. Army. In his early 20s, he began drinking heavily and exhibiting behavior that was so disruptive he ended up in military jail. He was seen by a psychologist, who diagnosed him with schizophrenia, and was eventually court martialed and discharged from the Army.

"He exhibits textbook symptoms of paranoia, delusional thoughts, auditory hallucinations, extreme disorganization in speech and environment," his mother

said. *"We can always detect when he has stopped his medication. He stops communicating with family, he loses his belongings, he starts to isolate in his room and he exhibits the symptom of anosognosia, which is lack of insight that his symptoms have returned. All of this led to jail, prison, homelessness cycles throughout... When his symptoms are actively present, he's unable to hold any type of job, manage finances, keep up with appointments..."*

An older Black woman with schizophrenia told of her use of drugs and alcohol, bouts of homelessness, the court-ordered removal of her children from her care and her attempt at suicide. *"It was a dark past of brokenness. And I lost my family because of homelessness."*

Schizophrenia can be a rollercoaster existence

Meeting participants described the stark contrast between best and worst days that can make life with schizophrenia an unpredictable rollercoaster. *"On his worst days, my son would become aggressive and violent and hateful, scaring me and his sisters,"* said one older

White woman whose son with schizophrenia is now deceased. *"He would take off and fly to foreign countries, and I would have to get him back home. He'd end up in jail, and I'd have to drive to wherever he was to pick him up."*

A middle-aged White man from North Carolina who cares for his 33-year-old son with schizoaffective disorder said these ups and downs affect everything from his son's housing, to his ability to work, to whether he can even manage basic daily activities. *"On his best days, my son is very high functioning, operates as a peer support specialist and is very engaged. On his worst days, he's very withdrawn, has challenges with his cognitive functioning, comfort being around others and going about his daily life."*

A woman from New Hampshire painted a stark and devastating picture of how schizophrenia has affected her adult son: *"On his best days, he socializes with people and can carry on a simple, uncomplicated conversation. On the most difficult days, he chants offensive words over and over and can't leave his bed."*



Meeting Topic 2: Views on current and future treatment approaches

Although most participants said they currently take antipsychotics and other psychiatric medications, many said these medicines did not control their symptoms adequately and caused troublesome side effects.

Nearly 80% of survey participants reported that oral or long-acting antipsychotic medications were their primary drug treatment. About one-third of caregivers and just

over 40% of patients also reported add-on treatment with antidepressants, anxiolytics and other medications (Figure 5).

Survey participants also reported high levels of medication switching and discontinuation. Eighty percent of patients said they switched medicines because the current one wasn't effective for them and/or had undesirable side effects (Figure 6).

FIGURE 5. Survey participant responses to “Are you currently taking any medications to manage your schizophrenia? Check all that apply.”

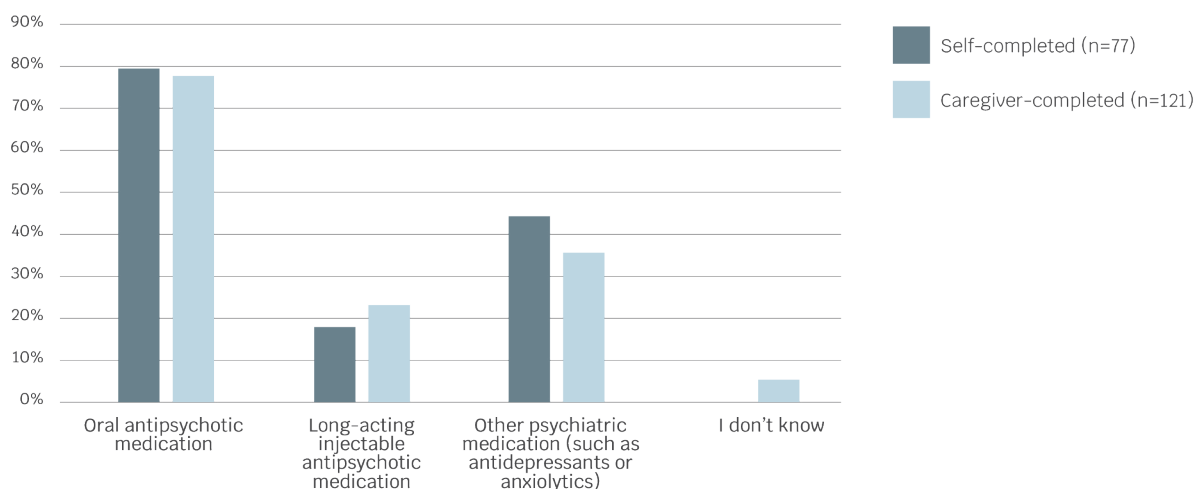
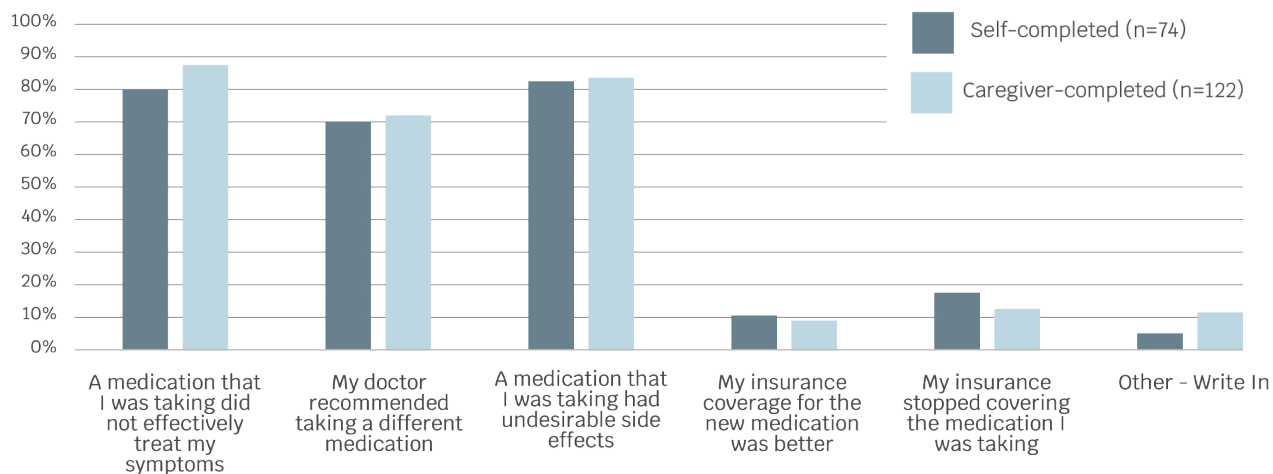


FIGURE 6. Survey participant responses to “Have you ever switched from one medication to another for the reasons below?”



Survey participants described a host of negative side effects from their schizophrenia treatments. Among patient respondents, the most common reason selected was weight gain. Among both patients and caregivers, the second most common reason for stopping treatment was that the medicine did not effectively treat the disease symptoms.

Other commonly noted reasons for stopping treatment were that the medicines caused movement disorders,

a flat affect (lack of emotion) and/or sexual problems (Figure 7).

When asked what they want most from future schizophrenia treatments, patients rated control of hallucinations and delusions as most important — but nearly all the benefits listed in Figure 8 were rated as moderately to very important to both patients and caregivers.

FIGURE 7. Survey participant responses to “Have you ever quit taking a medication prescribed to treat your schizophrenia for any of the following reasons?”

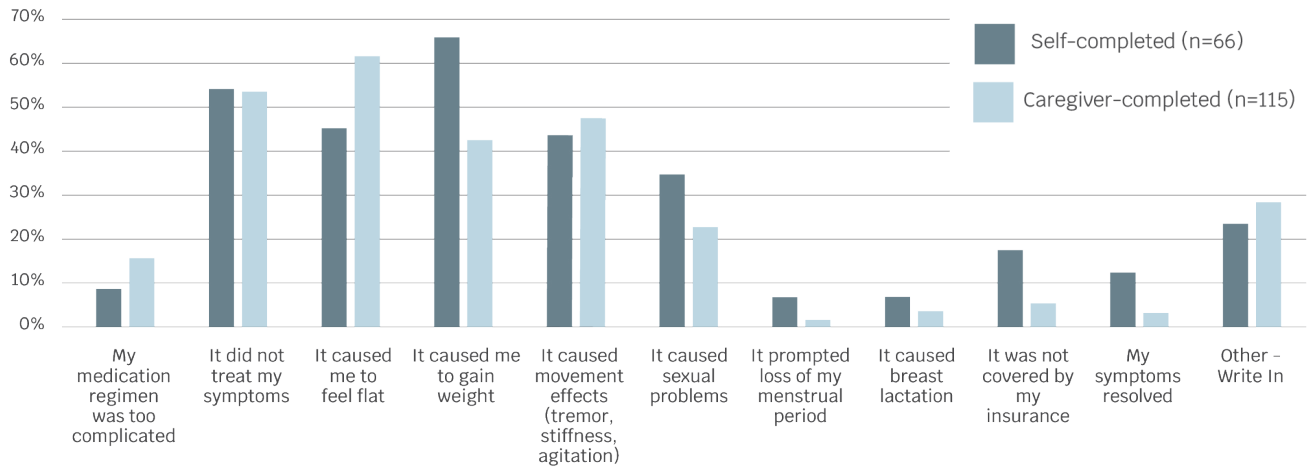
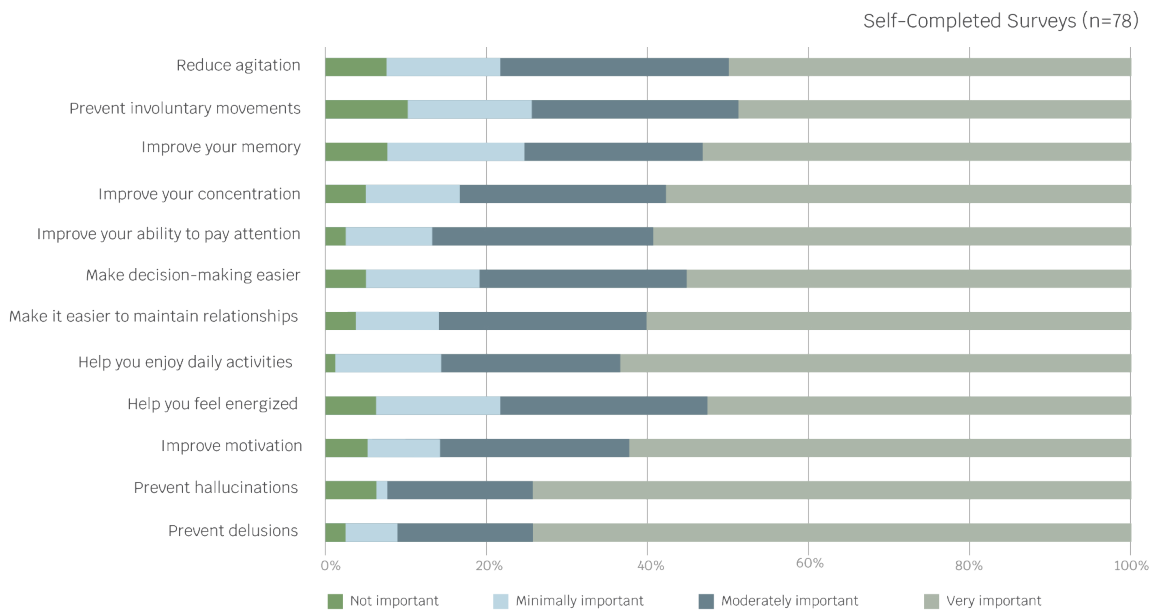


FIGURE 8. Survey participant responses to “When thinking about new treatments for schizophrenia, how important are the following?”



Lack of effectiveness, significant side effects can lead to years of searching for a treatment that works

Several meeting panelists expressed their frustration with the ineffectiveness and negative side effects of antipsychotic agents. An Asian woman in her 30s who was on the panel said she has tried two typical and five atypical antipsychotics during the course of her illness, which began in her early 20s but was not diagnosed until a few years later. She experienced tardive dyskinesia with one typical antipsychotic and weight gain with one atypical antipsychotic.

Since being diagnosed in 2011, she has been treated with three atypical agents. The first was ineffective, and the next two reduced her paranoia but not her delusions, which are currently being treated with psychotherapy. *“I believe good and bad things happen in the world and in this country because of my thoughts, actions and what I post on Twitter,”* she said. *“At the moment, I’m not sure if these delusions are real or not. Life is now a nightmare. The delusions take all my time.”*

“I’m extremely stressed out feeling the weight of the world on my shoulders. I’ve never been on an antipsychotic medication that works for these delusions,” she added. *“I dream of being on one that works, so I don’t have to live these nightmares, so I don’t believe these delusions... schizophrenia is a force of nature.”*

A White male panelist in his 30s described his 12-year search for an effective treatment. In addition to medication for schizoaffective disorder, his treatment regimen includes medicines for generalized anxiety disorder, obsessive-compulsive disorder, restless leg syndrome and insomnia. He is currently working with clinicians to determine the best treatment for the side effect of hyperprolactinemia (the excess production of milk-secreting hormone), and he still experiences delusions, paranoia and auditory hallucinations.

“On my good days, there’s little background noise, so I can deal with it,” he said. *“On my bad days, I have a hard time focusing on what I was doing. It takes a lot of energy to look calm.”*



I’m extremely stressed out feeling the weight of the world on my shoulders. I’ve never been on an antipsychotic medication that works for these delusions. I dream of being on one that works.”



“

We who live with schizophrenia deserve to live a healthy existence with medications that do not give us side effects.”



“

... It took me 10 years to find the right medication, and that's a long time.”

A 51-year-old woman in Illinois who spoke on the panel began experiencing auditory hallucinations and paranoid delusions in her late teens and was diagnosed with schizophrenia in 2004, when her family committed her to a state psychiatric hospital. *“The first antipsychotic medication I was on raised prolactin levels and made my breasts lactate, so I was weaned off that medication and placed on the antipsychotic medication I’m on now,”* she said.

“But I still struggle with the side effects of my medication, namely, weight gain and sleepiness,” she continued. *“The sleepiness affects me throughout the day, and I have to actively try to keep awake at work. This also does not help with weight gain because I am too tired to exercise... I can see why some of my peers are so resistant to [taking] their medications to stay well. It is because of the side effects. It would be wonderful if the medications that we need to stay well didn’t have to come at the cost of side effects... We who live with schizophrenia deserve to live a healthy existence with medications that do not give us side effects.”*

A woman from Texas summed up many of the problems people experience with antipsychotic agents in a written comment: *“The medications never fully helped my son, and the side effects were atrocious, including massive weight gain, tardive dyskinesia, flat affect, cognitive decline and an inability to stay awake during school hours and do his homework.”*

A White woman from Louisiana who was diagnosed with schizophrenia in 2008 said she wished for *“a way to come up with a more efficient method for figuring out which meds to take... It took me 10 years to find the right medication, and that’s a long time.”*

A treatment that can work — but access is heavily restricted

A White woman who spoke on the panel has a son whose schizoaffective disorder developed at age 18. “He was assigned to a community mental health clinic, where he received several different antipsychotic medications. None of the medications they used were very effective. His positive symptoms responded, and he was doing better, but [my son] still couldn’t work, he still couldn’t go to school and he just didn’t seem like the same person that he was before he got sick.”

After two psychiatrists told her this was the best she could expect for her son, she embarked on a search for a more effective treatment. Her son eventually tried clozapine — and has made a full recovery. “Approximately three months after starting clozapine,



If I hadn’t pressed for clozapine and really fought for it, [my son] would still be very sick today. He would probably be gravely disabled.”



[my son] kind of woke up and was able to read, able to study and eventually able to go back to college,” she said. “He’s currently enrolled in school, getting two college degrees and working a job at the university. If I hadn’t pressed for clozapine and really fought for it, [my son] would still be very sick today. He would probably be gravely disabled.”

This panelist contended that her son should not have had to suffer for so long with inferior treatments — and she shouldn’t have had to fight so hard to get him a treatment that worked for him. But because clozapine is heavily regulated by the FDA, many psychiatrists refuse to prescribe it and many pharmacies refuse to carry it.

“[My son] had to suffer for over a year taking a myriad of medications that just weren’t working very well for him, and it is unfortunate that the doctors at the community health clinic thought he was doing well, when really he had the opportunity to do much better.”

“One of our biggest worries is that [my son] will not be able to receive clozapine,” she said. “We worry about pharmacy problems, prescription problems, general lack of availability and we’re also very concerned that someday his wonderful doctor will retire and that we won’t find a doctor that will prescribe this important medication.”

Her son, a White man in his early 20s, also spoke during the meeting, describing the relative ineffectiveness of the antipsychotic treatments he initially received as well as their severe side effects. “I was taking a lot of different medications. A lot of them had really bad side effects. Eventually, I got on clozapine and other meds that worked adjunctively with it, like metformin and Lamictal [lamotrigine]. I’ve been on clozapine for over three years now. I’ve completely recovered. I can go to school. I have a job. I’ve lost the weight that I initially gained on other meds, and I’m living an active lifestyle.”

The woman expressed her wish for a change in the FDA’s complicated Risk Evaluation and Mitigation Strategy (REMS) system and the required regular laboratory visits for blood testing that discourage

psychiatrists from prescribing clozapine. She advocated for more widespread use of at-home finger-prick testing for absolute neutrophil count (ANC) to detect agranulocytosis, a very rare but serious clozapine side effect that predisposes patients to infections and that the REMS system was designed to detect.

A White man in his 20s who spoke on the panel was diagnosed with schizophrenia as a teenager and tried 13 different antipsychotic medications before clozapine, which he said “made me feel better right away.”

“Since starting clozapine, I fulfilled all the blood work requirements for REMS. It has been a major commitment. That was only possible because I have supportive parents and transportation. The blood testing and the REMS requirements have been a significant burden to overcome and have made it difficult to find doctors to treat my condition... My family and I live in constant fear that my clozapine will be interrupted. I live in constant fear that my doctor will drop me as a patient and that we will not be able to find another doctor to prescribe clozapine. I have a return of symptoms after missing even one dose. The symptoms are terrible and very difficult.”



The blood testing and the REMS requirements have been a significant burden to overcome and have made it difficult to find doctors to treat my condition... My family and I live in constant fear that my clozapine will be interrupted.”

Members of the audience who participated via webcast included an Asian man who was diagnosed with schizophrenia during his junior year of college. After several medication switches, he is being treated with clozapine and lithium. He described the pros and cons of his medication regimen as follows: “*Certainly, the upside is being able to be a professional. The downside is relatively minimal in that I have to sleep a few extra hours a day, like nine or 10 hours, which I think is a good cost. It’s a cost I’m willing to pay in exchange for a life free of delusions and hallucinations.*”

He added that “*future medication should have the benefit of reducing hallucinations and delusions, but also not interfere with cognitive function so that an individual can still pursue their passions.*”

An older White woman who participated in the discussion began experiencing symptoms of schizophrenia, including auditory hallucinations and delusions, in 1985. Her initial treatment with thioridazine caused a 100-pound weight gain. She switched to fluphenazine and several other antipsychotic agents, but all proved ineffective. However, a year after being prescribed



clozapine, she was symptom free. *“With the right medication, the right doctors, the right therapists, psychiatrists and family and friends, we can be on the road to recovery,”* she said.

One other positive treatment experience

A young woman from Jacksonville, Fla., who is living with schizoaffective disorder, bipolar type, shared her experience with clinical trials of various drug treatments for her serious mental illness. Since 2015, she said she has tried haloperidol, olanzapine, aripiprazole, paliperidone, ziprasidone, transdermal asenapine, lurasidone and quetiapine. She currently takes cariprazine. *“The difference in side effects and efficacy of this medication has been absolutely night and day.... With this new drug... I experience less sedation. I take it in the morning, which is the very first drug I’ve ever not taken before bed because it doesn’t make me as tired.”*



I’m worried that the drug pipeline will just shrivel up or that there will be no new innovation.”

Worries for the future

Some participants expressed apprehension about what the future may hold for people with schizophrenia and their caregivers.

An Asian woman with schizoaffective disorder shared this key concern: *“Mine’s about the pipeline of the medications coming through in the future. I’m worried that it’ll just shrivel up or that there will be no new innovation in the formulas, because I’m actually about to switch medications myself. I find my options are kind of limited based on my experience with all the other ones I’ve tried. So to have options in the future is really important to me.”*

Regarding the long-term effects of cognitive impairment caused by her condition, she added:

“I would worry a lot about getting dementia because the cognitive impairments, I’m afraid they’re going to get worse over time, and then when I’m older, then I won’t be able to take care of myself as well as I can now.”



INCORPORATING PATIENT AND CAREGIVER INPUT INTO A BENEFIT-RISK FRAMEWORK FOR SCHIZOPHRENIA

DIMENSION	EVIDENCE AND UNCERTAINTIES	CONCLUSIONS AND REASONS
Analysis of Condition	<p>One of the most disabling medical conditions:</p> <ul style="list-style-type: none"> • Substantially impedes ability to complete activities of daily living • Many people have thoughts of self-harm and some attempt suicide • Many people self-medicate with alcohol or drugs and some experience substance use disorder and/or drug overdoses • Frequent contact with criminal justice system either as victims of crimes or because they are arrested • Homelessness is not uncommon • Many people experience anosognosia or lack of insight about their condition 	<p>Multiple devastating impacts experienced by individuals:</p> <ul style="list-style-type: none"> • Relationships impacted / damaged • Early death • Patients often out of work, hospitalized or incarcerated • Poor judgment/bad decision making • Disability • Anosognosia keeps people from seeking treatment (or recognizing that they need it)
Current Treatment Options	<p>Multiple treatments used concurrently to treat positive symptoms more effectively and to address negative symptoms or cognition</p> <ul style="list-style-type: none"> • Long-acting injectable antipsychotics used in an attempt to help with adherence to treatment and overcome issues related to anosognosia • Many patients remain untreated or unsatisfactorily treated despite available options • Medication switching and discontinuation due to lack of effectiveness, side effects and/or anosognosia • 1/3 of patients have positive symptoms resistant to treatment • Desired effects: treat positive symptoms and negative symptoms and provide cognitive enhancement so patients want to stay on treatment • Desired tolerability: Efficacy to take away positive symptoms without negative side effects 	<p>Reasons untreated:</p> <ul style="list-style-type: none"> • Very often refractory to first-line therapies • Undesirable side effects including weight gain, sedation, extrapyramidal symptoms/tardive dyskinesia, seizures, myocarditis, neutropenia, agranulocytosis, diabetes • Access barriers, including those caused by the clozapine REMS • Unclear need often expressed by patients due to anosognosia

Conclusion and key takeaways

Schizophrenia is a severe, chronic brain disease that alters perception, thinking, emotions and behavior and renders many people unable to live normal lives. Its symptoms include hallucinations and delusions, flat affect, loss of motivation, inability to think clearly, poor problem-solving, disorganized behavior (cognitive dysfunction) and anosognosia. As a result, schizophrenia is one of the most highly disabling medical conditions, and fewer than 20% of those affected maintain paid employment.

Schizophrenia and its symptoms often lead to disability, disrupted relationships, substance use disorder, drug overdose, thoughts of self-harm, suicide attempts, accidental deaths, becoming a victim of crime, death at the hands of law enforcement officers, hospitalization, homelessness, arrest, incarceration for disruptive or criminal behavior, legal entanglements and job loss due to uncontrolled symptoms or discrimination.

KEY TAKEAWAYS FROM THIS MEETING AND THE PRE-MEETING SURVEY INCLUDE:

- Many patients spend years trying multiple medications to find one that works for them — and some have yet to find one.
- Many existing therapies can cause significant side effects that lead people with schizophrenia to stop taking them — risking a return of severe disease symptoms.
- Anosognosia is one of the cruelest symptoms, as it causes people with schizophrenia to lack awareness of their disease and often refuse treatment. If recognized, anosognosia can be addressed, but awareness of this symptom is low, and its effects leave patients' families feeling powerless.
- People with schizophrenia and those who care for them want new, better treatments that more effectively treat their delusions, hallucinations and other disabling symptoms — without severe side effects such as massive weight gain, movement disorders and excessive sleepiness.
- Meanwhile, those who have found success with clozapine want fewer regulatory restrictions so that they can more easily access treatment and avoid the anxiety that their doctor will stop prescribing it.

People with schizophrenia have the right to effective medicines just like anyone else with a serious disease. They deserve respect and recognition that they are people who want to live and thrive.



We are indebted to the people with schizophrenia and those who care for them who participated in this effort through the pre-meeting survey, the meeting itself and the post-meeting comments. We also deeply appreciate the FDA's partnership, as the EL-PFDD initiative provides a valuable forum for the most important voice in the treatment discussion: the patient.

Appendix 1: Meeting agenda

Reimagine Schizophrenia: Transforming How We Are Treated, Function and Thrive

Patient-Focused Drug Development Meeting

November 2, 2022 | 10:00 a.m. to 3:00 p.m. EDT

Meeting Agenda

10:00–10:05 a.m.

Welcome

Tim Franson, M.D., Meeting Moderator
Principal – Faegre Drinker Consulting

Paulie Benjamin, Meeting Co-Moderator
Schizophrenia Patient Advocate

10:05–10:10 a.m.

Opening Remarks

Mary Palafox, R.N.
Chair of the Board
Schizophrenia & Psychosis Action Alliance

10:10–10:20 a.m.

Overview of Patient-Focused Drug Development

Bernard Fischer, M.D.
Deputy Director, Division of Psychiatry, Office of Neuroscience
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

10:20–10:35 a.m.

Overview of Schizophrenia Symptoms and Treatment Approaches

Matcheri Keshavan, M.D.
Department of Psychiatry, Beth Israel Deaconess Medical Center
Stanley Cobb Professor of Psychiatry, Harvard Medical School

10:35–10:50 a.m. **Discussion Format Overview and Demographic Polling**
Tim Franson, Meeting Moderator
Paulie Benjamin, Meeting Co-Moderator

Topic 1: Symptoms of Schizophrenia and Impact on Daily Life

10:50–11:15 a.m. **Panel Remarks from People Living with Schizophrenia or Caregivers**

11:15 a.m.–12:30 p.m. **Facilitated Discussion**

12:30–1:00 p.m. **Break**

Topic 2: Views on Current Approaches to Treatment and Future Treatments

1:00–1:25 p.m. **Panel Remarks from People Living with Schizophrenia or Caregivers**

1:25–2:40 p.m. **Facilitated Discussion**

2:40–2:50 p.m. **Pre-Meeting Survey Data Presentation**
Terry Frangiosa, M.B.A.
Board Member
Schizophrenia & Psychosis Action Alliance

2:50–3:00 p.m. **Closing Remarks**
Tim Franson, Meeting Moderator
Paulie Benjamin, Meeting Co-Moderator

Appendix 2: Meeting speakers

Note: Given the stigma of schizophrenia and concerns around speaking about their experiences in a public setting, some meeting speakers preferred to be identified only by their first name or a first name and last initial.

Topic 1 Panel: Symptoms and Daily Impacts

- Paulie Benjamin, Living with Schizophrenia
- Anita Fisher, Caregiver of Person Living with Schizophrenia
- David Geiger, Living with Schizophrenia
- Zuhura Namibia, Living with Schizophrenia
- Julie B., Living with Schizoaffective Disorder

Topic 1 Discussion Starters: Symptoms and Daily Impacts

- Grace Lee, Living with Schizoaffective Disorder
- Dede Ranahan, Former Caregiver of a Person with Schizophrenia
- Samuel, Living with Schizophrenia
- Chris Fink, Caregiver of a Person with Schizophrenia

Topic 2 Panel: Current and Future Treatments

- Alicia J., Living with Schizophrenia
- Rachel S., Caregiver of Person Living with Schizoaffective Disorder
- Carson S., Living with Schizoaffective Disorder
- Steve M., Living with Schizoaffective Disorder
- Michael B., Living with Schizophrenia
- Lisa Guardiola, Living with Schizophrenia

Topic 2 Discussion Starters: Current and Future Treatments

- Sandy, Living with Schizophrenia
- Nora, Living with Schizophrenia
- Davy, Living with Schizophrenia
- Nicole Gillen, Caregiver of a Person with Schizophrenia

Other Speakers

- Tim Franson, M.D., Principal, Faegre Drinker Consulting, Meeting Moderator
- Paulie Benjamin, Schizophrenia Patient Advocate, Meeting Co-Moderator
- Mary Palafox, R.N., Chair of the Board, Schizophrenia & Psychosis Action Alliance
- Bernard Fischer, M.D., Deputy Director, Division of Psychiatry, Office of Neuroscience, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- Matcheri Keshavan, M.D., Department of Psychiatry, Beth Israel Deaconess Medical Center, Stanley Cobb Professor of Psychiatry, Harvard Medical School
- Terry Frangiosa, M.B.A., Board Member, Schizophrenia & Psychosis Action Alliance

Appendix 3: Meeting discussion and polling questions

During the November 2, 2022, Schizophrenia PFDD Meeting, people living with schizophrenia and caregivers of people living with schizophrenia were invited to participate in multiple ways. First, these participants had the opportunity to respond to online polling questions, the results of which were used as a discussion aid for the facilitated discussion sessions. During those discussion sessions, the moderators also posed questions from the discussion starters to participants in the live Zoom; audience members were invited to respond to these questions by calling in or submitting written responses. The discussion and polling questions are listed below.

Demographic Questions

1. Which best describes you?

- a. Person with schizophrenia
- b. Caregiver of a person with schizophrenia

2. Which of the following best describes your race or ethnicity? Select ALL that apply.

- a. American Indian or Alaska Native
- b. Asian
- c. Black or African American
- d. Hispanic or Latino
- e. Native Hawaiian or Other Pacific Islander
- f. White
- g. Another option not listed

3. With which gender do you most identify?

- a. Male
- b. Female
- c. Non-binary
- d. Other gender not listed

4. How old were you when you first experienced symptoms of schizophrenia?

- a. Younger than 18 years
- b. 18–29 years
- c. 30–39 years
- d. 40–49 years
- e. 50–59 years
- f. 60 years or older

5. During the past 30 days, how severe would you say your schizophrenia symptoms have been?

- g. No symptoms
- a. Mild
- b. Moderate
- a. Severe

Topic 1 Polling Questions: Schizophrenia Symptoms & Daily Impact

1. Which ONE symptom of schizophrenia has the greatest impact on your life or the life of the person for whom you care?

- a. Thoughts or fears related to cleanliness and contamination
- b. Difficulty tolerating uncertainty or disorganization
- c. Thoughts about losing control and harming yourself or others
- d. Repetitive behaviors
- e. Loss of motivation or interest in daily activities
- f. Seeing, hearing, tasting, smelling, or feeling things others do not
- g. Feeling convinced you are extremely special or talented
- h. Experiences with telepathy, psychic forces, or fortune telling
- i. Feeling afraid or like you are being watched
- j. Not trusting other people

2. In the last six months, which daily activity has been most difficult for you or the person for whom you care?

- a. Expressing emotions
- b. Controlling emotions
- c. Thinking clearly
- d. Relating to others
- e. Participating in conversations
- f. Concentrating on tasks
- g. Remembering things
- h. Learning new information
- i. Solving problems
- j. Making decisions
- k. Taking care of yourself
- l. Working

3. Have you ever experienced any of the following life events or circumstances? Select ALL that apply.

- a. Struggled with relationships
- b. Had difficulty with school or my job
- c. Lost my job or was expelled from school
- d. Was the victim of a crime or abuse
- e. Experienced homelessness
- f. Was arrested because of behaviors related to schizophrenia
- g. Needed legal services not related to arrest (help with legal guardianship, disability rights, other civil matters)

Topic 2 Polling Questions: Current and Future Schizophrenia Treatments

1. Are you currently taking any of the following kinds of medications to manage your schizophrenia? Select ALL that apply.

- a. Oral antipsychotic medication
- b. Long-acting injectable antipsychotic medication
- c. Other psychiatric medication (such as antidepressants or anxiolytics)
- d. Other not listed

2. Do you currently receive any of the following non-drug treatments? Select ALL that apply.

- a. Inpatient psychiatric treatment
- b. Substance use disorder treatment
- c. Outpatient treatment (therapy, counseling, support groups)
- d. Housing support services
- e. Employment or education support services
- f. None of the above

3. When thinking about new treatments for schizophrenia, what treatment effect would be most important to you?

- a. Prevent delusions
- b. Prevent hallucinations
- c. Improve motivation or energy
- d. Help you enjoy daily activities
- e. Make it easier to maintain relationships
- f. Make decision-making easier
- g. Improve concentration and memory
- h. Prevent involuntary movements
- i. Reduce agitation

4. Have you ever stopped taking a medication prescribed to treat your schizophrenia for any of the following reasons? Select ALL that apply.

- a. My medication regimen was too complicated
- b. It did not treat my symptoms
- c. It caused me to feel flat
- d. It caused me to gain weight
- e. It caused movement effects (tremor, stiffness, agitation)
- f. It caused sexual problems
- g. It prompted loss of my menstrual period
- h. It caused breast lactation
- i. Other not listed
- j. No – I have never stopped taking a medication for these reasons

5. Have you ever experienced any of the following challenges in accessing prescription medications for schizophrenia? Select ALL that apply.

- a. Delay in getting medication because of the lack of a clear diagnosis
- b. Difficulty finding a doctor who is able to prescribe the right medication
- c. Difficulty finding a pharmacy to fill a prescription my doctor has written
- d. Having to choose between paying for my medications or other expenses
- e. Switching insurance and no longer having coverage for my medication
- f. I have not experienced any challenges in accessing my medications

DISCUSSION QUESTIONS

Topic 1 Discussion Questions: Schizophrenia Symptoms & Daily Impact

- Of all the symptoms of schizophrenia, which have the most significant impact on you or your loved one's daily life?
- Are there specific activities that you or your loved one cannot do because of schizophrenia?
- How does schizophrenia affect you or your loved one on best and worst days? Describe your best days and your worst days.
- How have your schizophrenia symptoms changed over time?
- Have you ever lost a job, been homeless, been a victim of a crime, or been arrested/jailed as a result of your schizophrenia symptoms?
- What worries you most about your schizophrenia?

Topic 2 Discussion Questions: Current and Future Schizophrenia Treatments

- What are you or your loved one currently doing to treat your schizophrenia?
- How well does your current treatment regimen treat the most significant symptoms of your disease?
- What are the most significant downsides to your current treatment(s), and how do they affect your daily life?
- Have you ever stopped taking a medication to treat schizophrenia? If so, why?
- What factors do you take into account when considering a new treatment for your schizophrenia?
- Outside of cost and/or insurance coverage, have you experienced challenges accessing prescription medicines for schizophrenia?
- Short of a cure, what specific things would you look for in an ideal schizophrenia treatment?

Appendix 4: Pre-meeting survey protocol

Pre-Meeting Survey: Schizophrenia Patient-Focused Drug Development Meeting

What is the purpose of this survey?

The purpose of this survey is to gain greater understanding about what it is like to live with schizophrenia, and what individuals with schizophrenia want from drug treatments. This survey was commissioned by the Schizophrenia & Psychosis Action Alliance (S&PAA) in partnership with the American Foundation for Suicide Prevention, Mental Health America, the National Alliance on Mental Illness, and the National Council for Mental Wellbeing. We are hoping for responses from people living with schizophrenia in the United States, along with their caregivers. This research will help patient organizations, therapy developers, and the U.S. Food and Drug Administration (FDA) better understand what matters when it comes to symptoms, impacts on daily life, and development of new therapies. Survey results will inform planning for a **community-led meeting with the FDA in late 2022**. Summary results will also be shared in a public report after the meeting.

Who can participate?

This survey is for:

- Adults with schizophrenia who received their diagnosis at least six months ago
- Caregivers of adults with schizophrenia who are not able to complete this survey on their own behalf

It is not intended for professional, paid caregivers.

Respondents must live in the United States and have reached the age of majority, which is 19 years old in Alabama and Nebraska, 21 in Mississippi and Puerto Rico, and 18 in all other states.

What does the survey ask?

This survey asks for information about when and how you or the person you provide care for received a diagnosis

of schizophrenia and how the disease has affected your life or theirs. It includes questions about symptoms and their impact on things like relationships, work, school, and overall health. It also asks about experiences with drug treatments and other approaches to managing the disease, what you'd like to see from future drug treatments, and views about participating in research. Many questions are multiple choice. You will also have the option to note any other things that you would like us to know.

What do I need to know before continuing?

Participation is optional. If you begin the survey, you can stop at any time. Before beginning, you will be asked to complete an informed consent form. That form explains more about this research and how it will be used, as well as how your information will be protected. If you have any questions about this study, you can contact the research team via **this form**. You may also contact the Advarra Institutional Review Board (IRB) with questions about research participants' rights or read more **here**.

Action: Section Navigator

Are you an individual with schizophrenia or the caregiver of an individual with schizophrenia? Please select "Answer" next to whichever applies.

If you care for more than one person with schizophrenia, please complete separate surveys for each individual. You can do this by completing a survey for one individual and then returning to the survey homepage to complete the next.

Action: JavaScript
New JavaScript

Consent to Participate

Page description:

This form has important information about why this survey is being done, what participation involves, and how the information survey respondents provide will be used.

Page exit logic: Skip / Disqualify Logic

IF: (#1 Question “Please check each of the boxes below to indicate your understanding of these terms and consent to participate.

“ is not exactly equal to (“I have read this consent form, or it has been read to me. I understand the information in this form, have had an opportunity to ask questions, and have had my questions answered. If I have additional questions, I understand that I can contact the research team. I agree to participate in this study and agree that the information I provide can be used as described.”, “I have reached the age of majority (19 in Alabama and Nebraska, 21 in Mississippi and Puerto Rico, and 18 in all other states).”, “I live in the United States.”) OR #3 Question “Please enter your age in years” is less than “18”) THEN: Disqualify and display:

Thank you for your interest in this survey. This survey is only for individuals who have reached the age of majority, and respondents must indicate agreement with all terms listed on the prior page. If you are an individual with schizophrenia who is younger than the age of majority, we encourage you to ask your parent or legal guardian of majority age to complete the survey on your behalf. Please contact the research team if you have any questions.

What are the goals of this study?

You are being asked to participate in a research study about your experience living with schizophrenia. The study’s goals are to:

- Provide insight into the frequency, severity, and significance of symptoms experienced by people with the schizophrenia;
- Describe how schizophrenia symptoms impact daily life;
- Describe approaches that people with schizophrenia use to treat and manage the disease and its symptoms;
- Provide perspective on why people do or do not use medications prescribed for schizophrenia; and
- Identify desired outcomes of schizophrenia medications that might be developed in the future.

This survey was commissioned by the Schizophrenia and Psychosis Action Alliance (S&PAA) in partnership with the American Foundation for Suicide Prevention, Mental Health America, the National Alliance on Mental Illness, and the National Council for Mental Wellbeing. It is being conducted by Faegre Drinker Consulting (Faegre Drinker).

What will I do if I choose to participate?

You will be asked to complete a survey about your experience with schizophrenia and what you would like from therapies for schizophrenia. The survey should take about 15 minutes.

What are my rights as a research participant?

Participation in this study is voluntary. If you begin the survey, you can stop at any time. You do not have to answer any question you do not want to answer. You will not be penalized if you decide to quit the survey.

How will you use the information that you collect?

This research will help patient organizations, therapy developers, and the U.S. Food and Drug Administration (FDA) better understand what matters when it comes to symptoms, impacts on daily life, and development of new therapies. Survey results will inform planning for a community-led meeting with the FDA in late 2022. Summary results will also be shared in a public report after the meeting. Results of this study also may be used in subsequent publications and presentations. If results of this study are published or presented, individual names and other personally identifiable information will be removed. We may share the data we collect from you with other researchers but will not share any of your personal identifiable information.

What benefits will I get from participating?

This study is designed to learn more about the experiences and views of those living with and caring for people with schizophrenia. Study results may be used in the future to help individuals with schizophrenia, as well as their caregivers and families, and inform U.S. Food and Drug Administration decisions about therapies for schizophrenia. You are not likely to have any direct benefits from participating.

What are the risks or discomforts associated with participation?

This survey does not involve any significant physical risks. As with all research, there is a chance that confidentiality of the information we collect about you could be breached. We take steps to minimize this risk, as described below.

Because the survey asks about experiences with schizophrenia, it is possible that some questions could be upsetting. If you find yourself in distress, help is available:

- The NAMI HelpLine—800-950-6264 or info@nami.org—can offer sympathy and support and provide information about resources in your community.

To find a warmline in your area, dial 211, or go to www.211.info, for information on local social services.

- The American Foundation for Suicide Prevention provides information about suicide and preventing suicide as well as support for those affected by suicide. Reach the Crisis Text Line at crisistextline.org, call 1-800-273-8255, or text TALK to 741741 to connect with a trained crisis counselor for free, 24/7.
- The National Suicide Prevention Lifeline provides 24/7, free and confidential support for people in distress, prevention and crisis resources for you or your loved ones, and best practices for professionals. Find more information about the Lifeline at suicidepreventionlifeline.org or dial 800-273-8255.

How will the information I provide be protected?

This survey is hosted on the Alchemer platform, which encrypts data and can only be accessed through secure HTTPS. Data will be analyzed by a team of individuals from Faegre Drinker and S&PAA. All personal information collected via the survey will remain confidential to this team, and all information shared in papers or reports on this research will be deidentified. Additionally, any data stored for the long term or used in comparison to other data in future research will be de-linked from identity data. Neither S&PAA nor Faegre Drinker will sell your data. By submitting personal information through this survey or to a Faegre Drinker or S&PAA contact, you agree that Faegre Drinker and S&PAA may contact you with questions related to the survey.

Who can I contact if I have questions or concerns about this study?

If you have any questions about this study, you can contact the research team via this form. You may also contact Advarra Institutional Review Board (IRB) with questions about research participants' rights or read more here.

VALIDATION

Min. answers = 3 (if answered)

1. Please check each of the boxes below to indicate your understanding of these terms and consent to participate.

- I have read this consent form, or it has been read to me. I understand the information in this form, have had an opportunity to ask questions, and have had my questions answered. If I have additional questions, I understand that I can contact the research team. I agree to participate in this study and agree that the information I provide can be used as described.
- I have reached the age of majority (19 in Alabama and Nebraska, 21 in Mississippi and Puerto Rico, and 18 in all other states).
- I live in the United States.

2. Please sign this form by completing each of the fields below: *

First Name

Last Name

VALIDATION

Must be numeric Whole numbers only Positive numbers only

LOGIC

Hidden unless: QUESTION NOT FOUND! is one of the following answers [NO OPTIONS SET]

3. Please enter your age in years *

Part 1. Initial Symptoms and Diagnosis

Page description:

As you continue with this survey, you will be asked questions about initial schizophrenia symptoms and diagnosis, daily life, research, and disease management and treatment. Try to answer as accurately as you can. If you don't know the answer to a question, it is OK to leave it blank.

VALIDATION

Must be numeric Whole numbers only Positive numbers only

4. How many years old were you when...

You first experienced symptoms of schizophrenia?

You were officially diagnosed with schizophrenia?

5. Before receiving a diagnosis of schizophrenia, did you experience any of the following health-related events or circumstances? Check all that apply.

- Started eating less regularly
- Had trouble sleeping
- Increased use of alcohol or drugs
- Received treatment for substance use disorder
- Had thoughts of self-harm
- Attempted suicide
- Was hospitalized for psychiatric reasons

6. Before receiving a diagnosis of schizophrenia, did you experience any of the following life events or circumstances? Check all that apply.

- Struggled with relationships
- Had difficulty doing my job
- Lost my job
- Had difficulty in school
- Was expelled from school
- Was the victim of a crime or abuse
- Experienced homelessness
- Was arrested because of behaviors related to schizophrenia
- Was incarcerated in prison or jail
- Needed legal services not related to being arrested (for example, help with legal guardianship, disability rights, other civil matters)
- Needed increased special education or employment support services

7. Around the time you received a diagnosis of schizophrenia, did you experience any of the following? Check all that apply.

- Thoughts or fears related to cleanliness and contamination
- Difficulty tolerating uncertainty or disorganization
- Thoughts about harming yourself or others
- Repetitive behaviors such as frequent washing, cleaning, counting, or demanding reassurance
- Loss of motivation
- Loss of interest in daily activities
- Loss of interest in social activities
- Lack of energy
- Seeing, hearing, tasting, smelling, or feeling things that others did not
- Feeling convinced that you were extremely special or talented
- Experiences with telepathy, psychic forces, or fortune telling
- Feeling more afraid than usual
- Feeling you were being watched
- Not trusting other people
- Believing things others didn't believe

8. Around the time you received a diagnosis of schizophrenia, did you have difficulty with any of the following? Check all that apply.

- Expressing emotions
- Controlling emotions
- Speaking clearly so that others can understand me
- Thinking clearly
- Relating to others
- Focusing on conversations
- Concentrating on tasks
- Remembering things
- Learning new information
- Solving problems
- Making decisions
- Taking care of yourself
- Working
- Starting things and/or finishing things

9. Have any of your relatives been diagnosed with schizophrenia or a related condition? If so, please check the box(es) for anyone who has.

- No, not to my knowledge
- Brother or sister
- Cousin
- Parent
- Aunt or uncle
- Grandparent
- Niece or Nephew
- Other - Please Describe:

LOGIC

Show/hide trigger exists.

10. Before you were diagnosed with schizophrenia, did you receive any other diagnoses to explain the symptoms that you were experiencing?

- Yes
- No

LOGIC

Hidden unless: #10 Question “Before you were diagnosed with schizophrenia, did you receive any other diagnoses to explain the symptoms that you were experiencing?” is one of the following answers (“Yes”)

11. Did you receive any of the following diagnoses? Check all that apply.

- Anxiety (e.g., generalized anxiety disorder, social anxiety disorder, phobias)
- Attention deficit hyperactivity disorder (ADHD)
- Autism Spectrum Disorder
- Bipolar disorder
- Major depressive disorder (MDD)
- Post-traumatic stress disorder (PTSD)
- Borderline personality disorder
- Traumatic brain injury (TBI)
- Delusional disorder
- Obsessive compulsive disorder (OCD)
- Schizoaffective disorder
- Schizophreniform disorder
- Substance use disorder
- Other Diagnosis - Please Specify:

12. In addition to schizophrenia, do you currently have an official diagnosis of any of the following? Check all that apply.

- Anxiety, including generalized anxiety disorder, social anxiety disorder, and phobias
- Attention deficit hyperactivity disorder (ADHD)
- Autism Spectrum Disorder
- Bipolar disorder
- Borderline personality disorder
- Delusional disorder
- Major depressive disorder (MDD)
- Obsessive compulsive disorder
- Post-traumatic stress disorder (PTSD)
- Schizoaffective disorder
- Schizophreniform disorder
- Substance use disorder
- Traumatic brain injury (TBI)
- Other Diagnosis - Please Specify:

Part 2. Living with Schizophrenia: Symptoms

13. Schizophrenia may make it difficult to think, act, or live the way one wants.

Have any of the following diminished your ability to function and live the way you would like?

	No Impact	Minimal Impact	Moderate Impact	Significant Impact
Thoughts or fears related to cleanliness and contamination	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficulty tolerating uncertainty or disorganization	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Thoughts about losing control and harming yourself or others	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Repetitive behaviors such as frequent washing, cleaning, counting, or demanding reassurance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Loss of motivation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Loss of interest in daily activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Loss of interest in social activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of energy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Seeing, hearing, tasting, smelling, or feeling things that others do not	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling convinced that you were extremely special or talented	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Experiences with telepathy, psychic forces, or fortune telling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling more afraid than usual	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feelings of being watched	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Not trusting other people	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Believing something that others don't believe	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

14. In the past six months, have you had difficulty with any of the following?

	No	Minimal Difficulty	Moderate Difficulty	Significant Difficulty
Expressing emotions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Controlling emotions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Speaking so that others can understand me	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Thinking clearly	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Relating to others	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Focusing on conversations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Concentrating on tasks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Remembering things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Learning new information	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Solving problems	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Making decisions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Taking care of yourself	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Working	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Starting and/or finishing things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

15. In the past 12 months, have you done or experienced any of the following? Check all that apply. Please remember that all individual responses will remain confidential, and honest answers will help ensure that we are accurately representing the schizophrenia community.

- Received treatment for substance use disorder
- Been the victim of a crime or abuse
- Experienced homelessness
- Had thoughts of self-harm
- Attempted suicide
- Been hospitalized for psychiatric reasons
- Been arrested
- Been incarcerated in prison or jail
- Needed other legal services (including but not limited to legal guardianship, disability rights, other civil matters)
- Needed special education or employment support services beyond my usual needs
- Overdosed on drugs
- Other - Write In

16. How well do the below statements describe you and your experience today?

	Agree very much	Agree	Unsure	Disagree	Disagree very much
Some of the symptoms were made up by my mind	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I do not need medication	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The doctor is right in prescribing medication for me	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If someone told me that I had a mental illness they would be right	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My stay in the hospital was necessary	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
None of the unusual things I experienced are due to an illness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I do not need to be seen by a doctor or psychiatrist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am mentally well	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

VALIDATION

Must be numeric

17. From the time you received your schizophrenia diagnosis to today, about how many times have you experienced a setback or “recurrence” in your symptoms?

18. How severe would you say your schizophrenia symptoms have been...

	No symptoms	Mild	Moderate	Severe
During the past week	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
During the past 30 days	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

19. How much do your schizophrenia symptoms negatively impact your life...

	No Impact	Minimal Impact	Moderate Impact	Significant Impact
On the best days	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
On the worst days	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

VALIDATION

Max character count = 100

20. What have been the most significant impacts of schizophrenia on your life?

Part 3. Living with Schizophrenia: Daily Life

21. Which of these best describes your current living situation?

- Living independently, alone
- A household with relatives or friends
- Supervised group housing
- Partially supervised group housing
- Residential substance use program (e.g., sober house, halfway house)
- Supportive housing
- Long-term care facility, such as a nursing home, senior housing, or a skilled nursing facility
- Correctional facility (e.g., prison, jail)
- Shelter
- Currently without housing
- I don't know

22. Have you had any other living situations within the past 12 months? Check all that apply.

- Living independently, alone
- A household with relatives or friends
- Supervised group housing
- Partially supervised group housing
- Residential substance use program (e.g., sober house, halfway house)
- Supportive housing
- Long-term care facility, such as a nursing home, senior housing, or a skilled nursing facility
- Correctional facility (e.g., prison, jail)
- Shelter
- Currently without housing
- I don't know

23. Are you currently employed, or working for pay?

- Yes, full-time
- Yes, part-time
- Actively looking for work but not currently employed
- Not currently employed
- Retired
- Prefer not to say

24. Are you currently in school?

- Yes, full-time
- Yes, part-time
- No

25. Since you first started experiencing symptoms of schizophrenia, has your ability to do the following changed?

	Worsened significantly	Worsened	No change	Improved	Improved significantly	Not applicable
Maintain relationships	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Perform at work	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Perform in school	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Manage your responsibilities at home	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Manage your finances	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cope without alcohol or drugs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

26. Have you made any of the following changes in your career or education because of schizophrenia symptoms? Check all that apply.

- Cut back on hours at work
- Took a leave of absence from a job
- Took a leave of absence from school
- Switched to a job with fewer or more predictable hours
- Switched to a less challenging job
- Switched to a job that I was overqualified for
- Passed up a promotion or desired job change
- Postponed or cancelled future education plans
- Left the workforce altogether
- Took early retirement
- Other - Write In

27. Have you done any of the following in your personal life because of schizophrenia symptoms? Check all that apply.

- Avoided important social gatherings
- Stopped pursuing hobbies
- Avoided taking vacation
- Ended a romantic relationship
- None of the above
- Other - Write In

**28. Have you ever used or taken part in any of the following forms of support?
Check all that apply.**

- Financial support from family or friends
- Financial assistance from the government
- Disability insurance
- Supported employment
- Vocational rehabilitation other than supported employment
- Clubhouse program
- Respite care
- Other - Write In

LOGIC

Show/hide trigger exists.

29. Have you ever had a psychiatric advance directive (PAD) in place? This could include a conservatorship/guardianship, medical or mental health power of attorney, financial power of attorney, or court-mandated treatment.

- Yes
- No
- I don't know
- None of the above
- Other - Write In

LOGIC

Hidden unless: #29 Question "Have you ever had a psychiatric advance directive (PAD) in place? This could include a conservatorship/guardianship, medical or mental health power of attorney, financial power of attorney, or court-mandated treatment." is one of the following answers ("Yes")

30. Have you ever been under court-mandated treatment or conservatorship?

- Yes
- No
- I don't know

Part 4. Treating and Managing Schizophrenia

31. When thinking about new treatments for schizophrenia, how important is it that they...

	Not important	Minimally important	Moderately important	Very important
Prevent delusions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prevent hallucinations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improve motivation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Help you feel energized	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Help you enjoy daily activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Make it easier to maintain relationships	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Make decision-making easier	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improve your ability to pay attention	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improve your concentration	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prevent involuntary movements	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Reduce agitation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Enter another option <input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

32. About how many hours per week do you spend actively managing your schizophrenia? This can include time spent attending medical or therapy appointments, traveling to and from appointments, and spending time on your own dealing with or trying to improve symptoms.

- 0-5 hours
- 5-10 hours
- 10-15 hours
- 15-20 hours
- More than 20 hours

33. What types of non-drug treatment or support have you received? Are you receiving these currently?

	Not important	Minimally important
Inpatient psychiatric treatment	<input type="radio"/>	<input type="radio"/>
Substance use disorder treatment	<input type="radio"/>	<input type="radio"/>
Outpatient psychiatric or psychological treatment (therapy, counseling, or support groups)	<input type="radio"/>	<input type="radio"/>
Housing support services	<input type="radio"/>	<input type="radio"/>
Employment or education support services	<input type="radio"/>	<input type="radio"/>
None of the above <input type="text"/>	<input type="radio"/>	<input type="radio"/>

LOGIC

Show/hide trigger exists.

**34. Are you currently taking any medications to manage your schizophrenia?
Check all that apply.**

- Oral antipsychotic medication
- Long-acting injectable antipsychotic medication
- Other psychiatric medication (such as antidepressants or anxiolytics)

- Other - Write In

LOGIC

Hidden unless: #34 Question "Are you currently taking any medications to manage your schizophrenia? Check all that apply." is one of the following answers ("Oral antipsychotic medication", "Long-acting injectable antipsychotic medication", "Other psychiatric medication (such as antidepressants or anxiolytics)")

35. Do you take your medication(s) as prescribed by your doctor?

- Yes
- No
- I don't know

VALIDATION

Must be numeric

36. How many different schizophrenia medications have you taken since you were diagnosed with schizophrenia?

37. Have you ever switched from one medication to another for the reasons below? Check all that apply.

- A medication that I was taking did not effectively treat my symptoms
- My doctor recommended taking a different medication
- A medication that I was taking had undesirable side effects
- My insurance coverage for the new medication was better
- My insurance stopped covering the medication I was taking
- Other - Write In

LOGIC

38. Have you ever quit taking a medication prescribed to treat your schizophrenia for any of the following reasons? Check all that apply.

- My medication regimen was too complicated
- It did not treat my symptoms
- It caused me to feel flat
- It caused me to gain weight
- It caused movement effects (tremor, stiffness, agitation)
- It caused sexual problems
- It prompted loss of my menstrual period
- It caused breast lactation
- It was not covered by my insurance
- My symptoms resolved
- Other - Write In

Part 5. Research Studies

39. Have you participated in any of the following types of research studies? Check all that apply. If you don't know, select "I don't know."

- Natural history study for schizophrenia – These studies seek to understand how diseases progress or change over time, without treatment.
- Other observational study for schizophrenia – These include other studies that assess health outcomes but do not involve specific interventions, such as changes in diet, exercise, or use of medications or devices.
- Interventional study for schizophrenia that tested the effects of something other than a drug – Examples of interventional studies that are not for investigational drugs include studies for which participants might change their diets, exercise habits, or other activities.
- I don't know

LOGIC

Show/hide trigger exists.

40. Have you ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies.

- Yes
- No
- I don't know.

LOGIC

Hidden unless: #40 Question "Have you ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("Yes")

41. How much motivation, if any, did the following provide to participate in the trial?

	Not at all	Minimal Motivation	Moderate Motivation	Significant Motivation
Desire for clinical benefit and improved quality of life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to investigational drug	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to medical care	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to medical experts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Positive reputation of the study team	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Positive interactions with the study team	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Opportunity to help others with schizophrenia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Opportunity to contribute to science	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Support from their doctor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Suggested by another person whose family is impacted by the disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Suggested by a patient advocacy organization	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

LOGIC

Hidden unless: #40 Question "Have you ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("Yes")

42) Did any of the following cause concern about participation in the trial? Check all that apply.

- Concern about not being accepted into the trial
- Uncertainty about the safety of the study drug
- Uncertainty about whether potential benefits would justify potential risks
- Fear of receiving placebo
- Fear of physical and/or mental pain that could accompany required tests
- Uncertainty about whether the study requirements would allow me to manage their schizophrenia in the way that I'd like
- Time required
- Travel required
- Long-term commitment required
- Complexity of the study logistics
- Concern about loss of control
- Level of compensation for participation
- Other - Write In:

LOGIC

Show/hide trigger exists. Hidden unless: #40 Question "Have you ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("Yes")

43) Would you consider joining a clinical trial again?

- Yes
- No
- I don't know

LOGIC

Logic: Hidden unless: #43 Question "Would you consider joining a clinical trial again?" is one of the following answers ("No")

44) Why not?

LOGIC

Hidden unless: #40 Question "Have you ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("No")

45) Before taking this survey, were you aware that there are research studies on new medications that haven't yet been proven effective but might be?

- Yes
- No
- I don't know

LOGIC

Hidden unless: #40 Question "Have you ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("No")

46) Have you ever tried to participate in a clinical trial but have not been eligible?

- Yes
- No
- I don't know

LOGIC

Hidden unless: #40 Question "Have you ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("No")

47) Would you consider joining a clinical trial in the future?

- Yes
- No
- I don't know

LOGIC

Hidden unless: #40 Question "Have you ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("No","I don't know")

48) If you were given the chance to participate in a clinical trial, how much motivation do you think the following would provide to participate?

	Not at all	Minimal Motivation	Moderate Motivation	Significant Motivation
Desire for clinical benefit and improved quality of life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to investigational drug	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to medical care	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to medical experts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Positive reputation of the study team	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Positive interactions with the study team	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Opportunity to help others with schizophrenia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Opportunity to contribute to science	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Support from their doctor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Suggested by another person whose family is impacted by the disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Suggested by a patient advocacy organization	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

LOGIC

Hidden unless: #40 Question "Have you ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("No","I don't know")

49) If you were given the chance to participate in a clinical trial in the future, how much concern do you think the following might cause you?

	No Concern	Minimal Concern	Moderate Concern	Significant Concern
Concern about not being accepted into the trial	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Uncertainty about the safety of the study drug	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Uncertainty about whether potential benefits would justify potential risks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fear of receiving placebo	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fear of physical and/or mental pain that could accompany required tests	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Uncertainty about whether the study requirements would allow me to manage their schizophrenia in the way that I'd like	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Time required	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Travel required	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Long-term commitment required	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Complexity of the study logistics	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Concern about loss of control	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Level of compensation for participation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Part 6. General Health Information

50) In general, would you say your health is:

- Excellent
- Very Good
- Good
- Fair
- Poor

51) Compared to one year ago, how would you rate your health in general now?

- Much better now than one year ago
- Somewhat better now than one year ago
- About the same
- Somewhat worse now than one year ago
- Much worse now than one year ago

52) During the past 4 weeks, has your physical health caused any of the following problems with your work or other regular daily activities?

	Yes	No
Cut down the amount of time you spent on work or other activities	<input type="radio"/>	<input type="radio"/>
Accomplished less than you would like	<input type="radio"/>	<input type="radio"/>
Were limited in the kind of work or other activities	<input type="radio"/>	<input type="radio"/>
Had difficulty performing the work or other activities (for example, it took extra effort)	<input type="radio"/>	<input type="radio"/>

53) During the past 4 weeks, has your mental or emotional health caused any of the following problems with your work or other regular daily activities?

	Yes	No
Cut down the amount of time you spent on work or other activities	<input type="radio"/>	<input type="radio"/>
Accomplished less than you would like	<input type="radio"/>	<input type="radio"/>
Didn't do work or other activities as carefully as usual	<input type="radio"/>	<input type="radio"/>

54) How TRUE or FALSE is each of the following statements for you.

	1 – Definitely true	2 – Mostly true	3 - Don't know	4 – Mostly false	5 – Definitely false
I seem to get sick a little easier than other people	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am as healthy as anybody I know	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I expect my health to get worse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My health is excellent	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

55) Have you been diagnosed with any of these medical conditions? Check all that apply.

- High Blood Pressure/Hypertension
- High Cholesterol/Hyperlipidemia
- Heart Disease/Heart Failure
- Diabetes
- Kidney Disease
- Liver Disease (Cirrhosis/Hepatitis)
- Respiratory Disease (COPD, Asthma)
- Other - Please specify: *

56) Do you currently use of any of the following? Check all that apply and try to answer honestly, knowing that all individual responses will remain confidential to our survey team.

	Never	Rarely	Sometimes	Often
Alcohol	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tobacco, including smoking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Marijuana	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prescription opioid	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Any illicit substances	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Part 7. Demographic Information

LOGIC

Page exit logic: Skip / Disqualify Logic IF: TRUE is always true THEN: Jump to page 19 - Thank You & Invitation to Participate in Patient-Focused Drug Development Meeting

This is the last section of our survey. It asks for information that will help us to create a more complete picture of how schizophrenia affects different people. Once again, all individual responses will remain confidential. Completion of this final section will help us better represent the schizophrenia community's experiences and perspectives.

57) With which gender do you most identify?

- Male
- Female
- Non-binary
- Another identity not listed:
- Prefer not to answer

58) Are you Hispanic, Latino, or of Spanish origin?

- Yes
- No
- Prefer not to answer

59) Which of the following best describe(s) you? Check all that apply.

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White
- Another identity not listed:(please specify):
- Prefer not to answer

60) What is the highest level of education that you have completed?

- Some high school
- High school
- Associate's degree or equivalent
- Bachelor's degree
- Master's degree
- Doctoral degree
- Prefer not to answer

61) What type(s) of insurance do you have? Check all that apply.

- Employer-sponsored health insurance
- Commercial health insurance obtained through the marketplace
- Medicare
- Medicaid
- Short-term disability insurance
- Long-term disability insurance
- Other, please specify:
- None
- I don't know
- Prefer not to answer

Consent to Participate (Caregivers)

This form has important information about why this survey is being done, what participation involves, and how the information survey respondents provide will be used.

LOGIC

Page exit logic: Skip / Disqualify Logic IF: (#62 Question "Please check each of the boxes below to indicate your understanding of these terms and consent to participate." is not exactly equal to ("I have read this consent form, or it has been read to me. I understand the information in this form, have had an opportunity to ask questions, and have had my questions answered. If I have additional questions, I understand that I can contact the research team. I agree to participate in this study and agree that the information I provide can be used as described.", "I have reached the age of majority (19 in Alabama and Nebraska, 21 in Mississippi and Puerto Rico, and 18 in all other states).", "I live in the United States.", "As a caregiver, I confirm that I am authorized to complete this survey on behalf of the person for whom I care and consent to the use of their information in research.") OR #65 Question "Please enter your age in years" is less than "18") THEN: Disqualify and display: "Thank you for your interest in this survey. This survey is only for individuals who have reached the age of majority, and respondents must indicate agreement with all terms listed on the prior page. If you are an individual with schizophrenia who is younger than the age of majority, we encourage you to ask your parent or legal guardian of majority age to complete the survey on your behalf. Please contact the research team if you have any questions."

What are the goals of this study?

You are being asked to participate in a research study about the experiences of an individual with schizophrenia for whom you provide care. The study's goals are to:

- Provide insight into the frequency, severity, and significance of symptoms experienced by people with the schizophrenia;
- Describe how schizophrenia symptoms impact daily life;
- Describe approaches that people with schizophrenia use to treat and manage the disease and its symptoms;
- Provide perspective on why people do or do not use medications prescribed for schizophrenia; and
- Identify desired outcomes of schizophrenia medications that might be developed in the future.

This survey was commissioned by the Schizophrenia and Psychosis Action Alliance (S&PAA) in partnership with the American Foundation for Suicide Prevention, Mental Health America, the National Alliance on Mental Illness, and the National Council for Mental Wellbeing. It is being conducted by Faegre Drinker Consulting (Faegre Drinker).

What will I do if I choose to participate?

You will be asked to complete a survey about the experiences that the person you care for has had with schizophrenia, and what you believe they would like from therapies for schizophrenia. The survey should take about 15 minutes.

What are my rights as a research participant?

Participation in this study is voluntary. If you begin the survey, you can stop at any time. You do not have to answer any question you do not want to answer. You will not be penalized if you decide to quit the survey.

How will you use the information that you collect?

This research will help patient organizations, therapy developers, and the U.S. Food and Drug Administration (FDA) better understand what matters when it comes to symptoms, impacts on daily life, and development of new therapies. Survey results will inform planning for a community-led meeting with the FDA in late 2022. Summary results will also be shared in a public report after the meeting. Results of this study also may be used in subsequent publications and presentations. If results of this study are published or presented, individual names and other personally identifiable information will be removed. We may share the data we collect from you with other researchers but will not share any of your personal identifiable information.

What benefits will I get from participating?

This study is designed to learn more about the experiences and views of those living with and caring for people with schizophrenia. Study results may be used in the future to help individuals with schizophrenia, as well as their caregivers and families, and inform U.S. Food and Drug Administration decisions about therapies for schizophrenia. You are not likely to have any direct benefits from participating.

What are the risks or discomforts associated with participation?

This survey does not involve any significant physical risks. As with all research, there is a chance that confidentiality of the information we collect about you could be breached. We take steps to minimize this risk, as described below.

Because the survey asks about experiences with schizophrenia, it is possible that some questions could be upsetting. If you find yourself in distress, help is available:

- The NAMI HelpLine—800-950-6264 or info@nami.org—can offer sympathy and support and provide information about resources in your community. To find a warmline in your area, dial 211, or go to www.211.info, for information on local social services.

- The American Foundation for Suicide Prevention provides information about suicide and preventing suicide as well as support for those affected by suicide. Reach the Crisis Text Line at crisistextline.org, call 1-800-273-8255, or text TALK to 741741 to connect with a trained crisis counselor for free, 24/7.
- The National Suicide Prevention Lifeline provides 24/7, free and confidential support for people in distress, prevention and crisis resources for you or your loved ones, and best practices for professionals. Find more information about the Lifeline at suicidepreventionlifeline.org or dial 800-273-8255.

How will the information I provide be protected?

This survey is hosted on the Alchemer platform, which encrypts data and can only be accessed through secure HTTPS. Data will be analyzed by a team of individuals from Faegre Drinker and S&PAA. All personal information collected via the survey will remain confidential to this team, and all information shared in papers or reports on this research will be de-identified. Additionally, any data stored for the long term or used in comparison to other data in future research will be de-linked from identity data. Neither S&PAA nor Faegre Drinker will sell your data. By submitting personal information through this survey or to a Faegre Drinker or S&PAA contact, you agree that Faegre Drinker and S&PAA may contact you with questions related to the survey.

Who can I contact if I have questions or concerns about this study?

If you have any questions about this study, you can contact the research team via this form. You may also contact Advarra Institutional Review Board (IRB) with questions about research participants' rights or read more here.

VALIDATION

Min. answers = 3 (if answered)

62) Please check each of the boxes below to indicate your understanding of these terms and consent to participate.*

- I have read this consent form, or it has been read to me. I understand the information in this form, have had an opportunity to ask questions, and have had my questions answered. If I have additional questions, I understand that I can contact the research team. I agree to participate in this study and agree that the information I provide can be used as described.
- I have reached the age of majority (19 in Alabama and Nebraska, 21 in Mississippi and Puerto Rico, and 18 in all other states).
- I live in the United States.
- As a caregiver, I confirm that I am authorized to complete this survey on behalf of the person for whom I care and consent to the use of their information in research.

63) Information about the Person for Whom You Care *

First Name:

Last Name:

Age in Years (Number):

64) Please sign this form by completing each of the fields below: *

First Name:

Last Name:

VALIDATION

Must be numeric Whole numbers only Positive numbers only

65) Please enter your age in years

Part 1. Initial Symptoms and Diagnosis (Caregiver Questions)

As you continue with this survey, you will be asked questions about initial schizophrenia symptoms and diagnosis, daily life, research, and disease management and treatment. Please answer on behalf of the person you care for, and try to answer as accurately as you can. If you don't know the answer to a question, it is OK to leave it blank.

VALIDATION

Must be numeric Whole numbers only Positive numbers only

66) How many years old was the person you care for when...

They first experienced symptoms of schizophrenia?:

They were officially diagnosed with schizophrenia?:

67) Before receiving a diagnosis of schizophrenia, did the person you care for experience any of the following health-related events or circumstances? Check all that apply.

- Started eating less regularly
- Had trouble sleeping
- Increased use of alcohol or drugs
- Received treatment for substance use disorder
- Had thoughts of self-harm
- Attempted suicide
- Was hospitalized for psychiatric reasons

68) Before receiving a diagnosis of schizophrenia, did the person you care for experience or do any of the following life events or circumstances? Check all that apply.

- Struggled with relationships
- Had difficulty doing their job
- Lost their job
- Had difficulty in school
- Was expelled from school
- Was the victim of a crime or abuse
- Experienced homelessness
- Was arrested because of behaviors related to schizophrenia
- Was incarcerated in prison or jail
- Needed legal services not related to being arrested (for example, help with legal guardianship, disability rights, other civil matters)
- Needed increased special education or employment support services

69) Around the time the person you care for received a diagnosis of schizophrenia, did they experience any of the following? Check all that apply.

- Thoughts or fears related to cleanliness and contamination
- Difficulty tolerating uncertainty or disorganization
- Thoughts about harming themselves or others
- Repetitive behaviors such as frequent washing, cleaning, counting, or demanding reassurance
- Loss of motivation
- Loss of interest in daily activities
- Loss of interest in social activities
- Lack of energy
- Seeing, hearing, tasting, smelling, or feeling things that others did not
- Feeling convinced that you were extremely special or talented
- Experiences with telepathy, psychic forces, or fortune telling
- Feeling more afraid than usual
- Feeling they were being watched
- Not trusting other people
- Believing things others didn't believe

70) Around the time the person you care for received a diagnosis of schizophrenia, did they have difficulty with any of the following? Check all that apply.

- Expressing emotions
- Controlling emotions
- Speaking clearly so that others can understand them
- Thinking clearly
- Relating to others
- Focusing on conversations
- Concentrating on tasks
- Remembering things
- Learning new information
- Solving problems
- Making decisions
- Taking care of themselves
- Working
- Starting and/or finishing things

71) Have any relatives of the person you care for been diagnosed with schizophrenia or a related condition? If so, please check the box(es) for anyone who has.

- No, not to my knowledge
- Brother or sister
- Cousin
- Parent
- Aunt or uncle
- Grandparent
- Niece or Nephew
- Other - Please Describe:

72) Before the person you care for was diagnosed with schizophrenia, did they receive any other diagnoses to explain the symptoms that they were experiencing?

- Yes
- No

LOGIC

Logic: Hidden unless: #10 Question "Before you were diagnosed with schizophrenia, did you receive any other diagnoses to explain the symptoms that you were experiencing?" is one of the following answers ("Yes")

73) Did they receive any of the following diagnoses? Check all that apply.

- Anxiety (e.g., generalized anxiety disorder, social anxiety disorder, phobias)
- Attention deficit hyperactivity disorder (ADHD)
- Autism Spectrum Disorder
- Bipolar disorder
- Major depressive disorder (MDD)
- Post-traumatic stress disorder (PTSD)
- Borderline personality disorder
- Traumatic brain injury (TBI)
- Delusional disorder
- Obsessive compulsive disorder (OCD)
- Schizoaffective disorder
- Schizophreniform disorder
- Substance use disorder
- Other Diagnosis - Please Specify:

74) In addition to schizophrenia, does the person you care for currently have an official diagnosis of any of the following? Check all that apply.

- Anxiety, including generalized anxiety disorder, social anxiety disorder, and phobias
- Attention deficit hyperactivity disorder (ADHD)
- Autism Spectrum Disorder
- Bipolar disorder
- Borderline personality disorder
- Delusional disorder
- Major depressive disorder (MDD)
- Obsessive compulsive disorder
- Post-traumatic stress disorder (PTSD)
- Schizoaffective disorder
- Schizophreniform disorder
- Substance use disorder
- Traumatic brain injury (TBI)
- Other Diagnosis - Please Specify:

Part 2. Living with Schizophrenia: Symptoms (Caregiver Questions)

75) Schizophrenia may make it difficult to think, act, or live the way one wants.

Have any of the following diminished the ability of the person you care for to function and live the way they would like?

	No Impact	Minimal Impact	Moderate Impact	Significant Impact
Thoughts or fears related to cleanliness and contamination	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficulty tolerating uncertainty or disorganization	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Thoughts about losing control and harming yourself or others	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Repetitive behaviors such as frequent washing, cleaning, counting, or demanding reassurance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Loss of motivation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Loss of interest in daily activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Loss of interest in social activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of energy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Seeing, hearing, tasting, smelling, or feeling things that others do not	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling convinced that you were extremely special or talented	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Experiences with telepathy, psychic forces, or fortune telling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling more afraid than usual	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feelings of being watched	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Not trusting other people	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Believing something that others don't believe	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

76) In the past six months, has the person you care for had difficulty with any of the following?

	No Difficulty	Minimal Difficulty	Moderate Difficulty	Significant Difficulty
Expressing emotions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Controlling emotions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Speaking so that others can understand me	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Thinking clearly	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Relating to others	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Focusing on conversations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Concentrating on tasks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Remembering things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Learning new information	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Solving problems	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Making decisions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Taking care of yourself	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Working	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Starting and/or finishing things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

77) In the past 12 months, has the person you care for done or experienced any of the following? Check all that apply. Please remember that all individual responses will remain confidential, and honest answers will help ensure that we are accurately representing the schizophrenia community.

- Received treatment for substance use disorder
- Been the victim of a crime or abuse
- Been hospitalized for psychiatric reasons
- Had thoughts of self-harm
- Attempted suicide
- Experienced homelessness
- Been arrested
- Been incarcerated in prison or jail
- Needed other legal services (including but not limited to legal guardianship, disability rights, other civil matters)
- Needed special education or employment support services beyond their usual needs
- Overdosed on drugs
- Other - Write In:

78) How well do the below statements describe the person you care for and what they think about their experience today?

	Agree Very Much	Agree	Unsure	Disagree	Disagree very much
Some of the symptoms were made up by their mind	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
They do not need medication	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The doctor is right in prescribing medication for them	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If someone told them that I had a mental illness they would be right	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Their stay in the hospital was necessary	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
None of the unusual things they experienced are due to an illness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
They do not need to be seen by a doctor or psychiatrist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
They are mentally well	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

VALIDATION

Must be numeric

79) From the time the person you care for received their schizophrenia diagnosis to today, about how many times have they experienced a setback or “recurrence” in their symptoms?

80) How severe have the schizophrenia symptoms of the person you care for been...

	No symptoms	Mild	Moderate	Severe
During the past week	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
During the past 30 days	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

81) How much do schizophrenia symptoms negatively impact the life of the person you care for...

	No Impact	Minimal Impact	Moderate Impact	Significant Impact
On the best days	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
On the worst days	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

VALIDATION

Max character count = 100

82) What have been the most significant impacts of schizophrenia on their life?

Part 3. Living with Schizophrenia: Daily Life (Caregiver Questions)**83) Which of these best describes the current living situation of the person for whom you care?**

- Living independently, alone
- A household with relatives or friends
- Supervised group housing
- Partially supervised group housing
- Residential substance use program (e.g., sober house, halfway house)
- Supportive housing
- Long-term care facility, such as a nursing home, senior housing, or a skilled nursing facility
- Correctional facility (e.g., prison, jail)
- Shelter
- Currently without housing
- I don't know

84) Has the person you care for had any other living situations within the past 12 months? Check all that apply.

- Living independently, alone
- A household with relatives or friends
- Supervised group housing
- Partially supervised group housing
- Residential substance use program (e.g., sober house, halfway house)
- Supportive housing
- Long-term care facility, such as a nursing home, senior housing, or a skilled nursing facility
- Correctional facility (e.g., prison, jail)
- Shelter
- Currently without housing
- I don't know

85) Is the person you care for currently employed, or working for pay?

- Yes, full-time
- Yes, part-time
- Actively looking for work but not currently employed
- Not currently employed
- Retired
- Prefer not to say

86) Is the person you care for currently in school?

- Yes, full-time
- Yes, part-time
- No
- I don't know

87) Since the person you care for first started experiencing symptoms of schizophrenia, has their ability to do the following changed?

	Worsened significantly	Worsened	No change	Improved	Improved significantly	Not applicable
Manage relationships	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Perform in their job	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Type of job that they can hold	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Perform in school	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Manage their responsibilities at home	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Manage their finances	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cope without alcohol or drugs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

88) Has the person you care for made any of the following changes in their career or education because of schizophrenia symptoms? Check all that apply.

- Cut back on hours at work
- Took a leave of absence from a job
- Took a leave of absence from school
- Switched to a job with fewer or more predictable hours
- Switched to a less challenging job
- Switched to a job that they were overqualified for
- Passed up a promotion or desired job change
- Postponed or cancelled future education plans
- Left the workforce altogether
- Took early retirement

Other - Write In:

89) Has the person you care for done any of the following because of schizophrenia symptoms? Check all that apply.

- Avoided important social gatherings
- Stopped pursuing hobbies
- Avoided taking vacation
- Ended a romantic relationship
- None of the above
- Other - Write In:

90) Has the person you care for ever used or taken part in any of the following forms of support? Check all that apply.

- Financial support from family or friends
- Financial assistance from the government
- Disability insurance
- Supported employment
- Vocational rehabilitation other than supported employment
- Clubhouse program
- Respite care
- Other - Write In:

91) Has the person you care for ever had a psychiatric advance directive (PAD) in place? This could include a conservatorship/guardianship, medical or mental health power of attorney, financial power of attorney, or court-mandated treatment.

- Yes
- No
- I don't know

LOGIC

Hidden unless: #29 Question "Have you ever had a psychiatric advance directive (PAD) in place? This could include a conservatorship/guardianship, medical or mental health power of attorney, financial power of attorney, or court-mandated treatment." is one of the following answers ("Yes")

92) Have they ever been under court-mandated treatment or conservatorship?

- Yes
- No
- I don't know

Part 4. Treating and Managing Schizophrenia (Caregiver Questions)

93) When thinking about new treatments for schizophrenia, how important to them would it be that treatments...

	Not important	Minimally important	Moderately important	Very important
Prevent delusions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prevent hallucinations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improve motivation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Help them feel energized	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Help them enjoy daily activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Make it easier to maintain relationships	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Make decision-making easier	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improve their ability to pay attention	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improve their concentration	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improve their memory	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prevent involuntary movements	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Reduce agitation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

94) About how many hours per week does the person you care for spend actively managing their schizophrenia? This can include time spent attending medical or therapy appointments, traveling to and from appointments, and spending time on their own dealing with or trying to improve symptoms.

- 0-5 hours
- 5-10 hours
- 10-15 hours
- 15-20 hours
- More than 20 hours

95) What types of non-drug treatment or support has the person you care for received? Are they receiving these currently?

	In the past	Currently
Inpatient psychiatric treatment	<input type="radio"/>	<input type="radio"/>
Substance use disorder treatment	<input type="radio"/>	<input type="radio"/>
Outpatient psychiatric or psychological treatment (therapy, counseling, or support groups)	<input type="radio"/>	<input type="radio"/>
Housing support services	<input type="radio"/>	<input type="radio"/>
Employment or education support services	<input type="radio"/>	<input type="radio"/>
None of the above	<input type="radio"/>	<input type="radio"/>

96) Is the person you care for currently taking any medications to manage their schizophrenia? Check all that apply.

- Oral antipsychotic medication
- Long-acting injectable antipsychotic medication
- Other psychiatric medication (such as antidepressants or anxiolytics)
- I don't know
- Other - Write In:

LOGIC

Hidden unless: #34 Question "Are you currently taking any medications to manage your schizophrenia? Check all that apply." is one of the following answers ("Oral antipsychotic medication", "Long-acting injectable antipsychotic medication", "Other psychiatric medication (such as antidepressants or anxiolytics)")

97) Does the person you care for take their medication(s) as prescribed by their doctor?

- Yes
- No
- I don't know

VALIDATION

Must be numeric

98) How many different schizophrenia medications has the person you care for taken since they were diagnosed with schizophrenia?

99) Has the person you care for ever switched from one medication to another for the reasons below? Check all that apply.

- A medication that they were taking did not effectively treat their symptoms
- Their doctor recommended taking a different medication
- A medication that they were taking had undesirable side effects
- Their insurance coverage for the new medication was better
- Their insurance stopped covering the medication they were taking
- Other - Write In:

100) Has the person you care for ever quit taking a medication prescribed to treat their schizophrenia for any of the following reasons? Check all that apply.

- Their medication regimen was too complicated
- It did not treat their symptoms
- It caused them to feel flat
- It caused them to gain weight
- It caused movement effects (tremor, stiffness, agitation)
- It caused sexual problems
- It prompted loss of their menstrual period
- It caused breast lactation
- It was not covered by their insurance
- Their symptoms resolved
- Other - Write In:

Part 5. Research Studies (Caregiver Questions)

101) Has the person you care for participated in any of the following types of research studies? Check all that apply. If you don't know, select "I don't know."

- Natural history study for schizophrenia – These studies seek to understand how diseases progress or change over time, without treatment.
- Other observational study for schizophrenia – These include other studies that assess health outcomes but do not involve specific interventions, such as changes in diet, exercise, or use of medications or devices
- Interventional study for schizophrenia that tested the effects of something other than a drug – Examples of interventional studies that are not for investigational drugs include studies for which participants might change their diets, exercise habits, or other activities.
- I don't know

LOGIC

Show/hide trigger exists.

102) Has the person you care for ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies.

- Yes
- No
- I don't know

LOGIC

Hidden unless: #102 Question "Has the person you care for ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("Yes")

103) How much motivation, if any, did the following provide to participate in the trial?

	Not at all	Minimal Motivation	Moderate Motivation	Significant Motivation
Desire for clinical benefit and improved quality of life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to investigational drug	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to medical care	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to medical experts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Positive reputation of the study team	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Positive interactions with the study team	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Opportunity to help others with schizophrenia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Opportunity to contribute to science	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Support from their doctor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Suggested by another person whose family is impacted by the disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Suggested by a patient advocacy organization	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

LOGIC

Hidden unless: #102 Question "Has the person you care for ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("Yes")

104) Did any of the following cause concern about participation in the trial? Check all that apply.

- Concern about not being accepted into the trial
- Uncertainty about the safety of the study drug
- Uncertainty about whether potential benefits would justify potential risks
- Fear of receiving placebo
- Fear of physical and/or mental pain that could accompany required tests
- Uncertainty about whether the study requirements would allow me to manage their schizophrenia in the way that I'd like
- Time required
- Travel required
- Long-term commitment required
- Complexity of the study logistics
- Concern about loss of control
- Level of compensation for participation
- Other - Write In:

LOGIC

Show/hide trigger exists. Hidden unless: #102 Question "Has the person you care for ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("Yes")

105) Would the person you care for consider joining a clinical trial again?

- Yes
- No
- I don't know

LOGIC

Hidden unless: #105 Question "Would the person you care for consider joining a clinical trial again?" is one of the following answers ("No")

106) Why not?

LOGIC

Hidden unless: #102 Question "Has the person you care for ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("No")

107) Before taking this survey, were you aware that there are research studies on new medications that haven't yet been proven to be effective but might be?

- Yes
- No
- I don't know

LOGIC

Hidden unless: #102 Question "Has the person you care for ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("No")

108) Has the person you care for ever tried to participate in a clinical trial but have not been eligible?

- Yes
- No
- I don't know

LOGIC

Hidden unless: #102 Question "Has the person you care for ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("No")

109) Would the person you care for consider joining a clinical trial in the future?

- Yes
- No
- I don't know

LOGIC

Hidden unless: #102 Question "Has the person you care for ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("No", "I don't know")

110) If the person you care for were given the chance to participate in a clinical trial, how much motivation do you think the following would provide to participate?

	Not at all	Minimal Motivation	Moderate Motivation	Significant Motivation
Desire for clinical benefit and improved quality of life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to investigational drug	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to medical care	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to medical experts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Positive reputation of the study team	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Positive interactions with the study team	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Opportunity to help others with schizophrenia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Opportunity to contribute to science	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Support from their doctor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Suggested by another person whose family is impacted by the disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Suggested by a patient advocacy organization	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

LOGIC

Hidden unless: #102 Question "Has the person you care for ever participated in a clinical trial for an investigational drug for schizophrenia? These studies test the safety and efficacy of medications to determine whether they should be approved for use outside of research studies." is one of the following answers ("No", "I don't know")

111) If the person you care for were given the chance to participate in a clinical trial in the future, how much concern do you think the following might cause them?

	No Concern	Minimal Concern	Moderate Concern	Significant Concern
Concern about not being accepted into the trial	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Uncertainty about the safety of the study drug	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Uncertainty about whether potential benefits would justify potential risks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fear of receiving placebo	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fear of physical and/or mental pain that could accompany required tests	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Uncertainty about whether the study requirements would allow me to manage their schizophrenia in the way that I'd like	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	No Concern	Minimal Concern	Moderate Concern	Significant Concern
Time required	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Travel required	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Long-term commitment required	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Complexity of the study logistics	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Concern about loss of control	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Level of compensation for participation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Part 6. General Health Information (Caregiver Questions)

112) In general, would you say health of the person you care for is:

- Excellent
- Very Good
- Good
- Fair
- Poor

113) Compared to one year ago, how would you rate the health of the person you care for in general now?

- Much better now than one year ago
- Somewhat better now than one year ago
- About the same
- Somewhat worse now than one year ago
- Much worse now than one year ago

114) During the past 4 weeks, has the physical health of the person you care for caused any of the following problems with their work or other regular daily activities?

	Yes	No
Cut down the amount of time they spent on work or other activities	<input type="radio"/>	<input type="radio"/>
Accomplished less than they would like	<input type="radio"/>	<input type="radio"/>
Were limited in the kind of work or other activities	<input type="radio"/>	<input type="radio"/>
Had difficulty performing the work or other activities (for example, it took extra effort)	<input type="radio"/>	<input type="radio"/>

115) During the past 4 weeks, has the mental or emotional health of the person you care for caused any of the following problems with their work or other regular daily activities?

	Yes	No
Cut down the amount of time they spent on work or other activities	<input type="radio"/>	<input type="radio"/>
Accomplished less than they would like	<input type="radio"/>	<input type="radio"/>
Didn't do work or other activities as carefully as usual	<input type="radio"/>	<input type="radio"/>

116) How TRUE or FALSE is each of the following statements for the person for whom you care.

	1 – Definitely true	2 – Mostly true	3 - Don't know	4 – Mostly false	5 – Definitely false
They seem to get sick a little easier than other people	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
They are as healthy as anybody they know	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
They expect their health to get worse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Their health is excellent	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

117) Has the person you care for been diagnosed with any of these medical conditions? Check all that apply.

- High Blood Pressure/Hypertension
- High Cholesterol/Hyperlipidemia
- Heart Disease/Heart Failure
- Diabetes
- Kidney Disease
- Liver Disease (Cirrhosis/Hepatitis)
- Respiratory Disease (COPD, Asthma)

Other - Please specify: *

118) Does the person you care for currently use of any of the following? Check all that apply and try to answer honestly, knowing that all individual responses will remain confidential to our survey team.

	Never	Rarely	Sometimes	Often	I don't know
Alcohol	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tobacco, including smoking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Marijuana	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Prescription opioid	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Any illicit substances	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Part 7. Demographic Information (Caregiver Questions)

LOGIC

Page exit logic: Skip / Disqualify Logic IF: TRUE is always true THEN: Jump to page 19 - Thank You & Invitation to Participate in Patient-Focused Drug Development Meeting

This is the last section of our survey. It asks for information that will help us to create a more complete picture of how schizophrenia affects different people. Once again, all individual responses will remain confidential. Completion of this final section will help us better represent the schizophrenia community's experiences and perspectives. Please complete the below fields for the person for whom you care.

119) With which gender does the person you care for most identify with?

- Male
- Female
- Non-binary
- Another identity not listed:
- Prefer not to answer

120) Is the person you care for Hispanic, Latino, or of Spanish origin?

- Yes
- No
- Prefer not to answer

121) Which of the following best describe(s) the person for whom you care? Check all that apply.

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White
- Another identity not listed:(please specify):
- Prefer not to answer

122) What is the highest level of education the person you care for has completed?

- Some high school
- High school
- Associate's degree or equivalent
- Bachelor's degree
- Master's degree
- Doctoral degree
- I don't know
- Prefer not to answer

123) What type(s) of insurance does the person you care for have? Check all that apply.

- Employer-sponsored health insurance
- Commercial health insurance obtained through the marketplace
- Medicare
- Medicaid
- Short-term disability insurance
- Long-term disability insurance
- Other, please specify:
- None
- I don't know
- Prefer not to answer

Thank You & Invitation to Participate in Patient-Focused Drug Development Meeting

We appreciate your participation in this research. The information you've shared about your experiences and attitudes will help our efforts to advance therapy development for schizophrenia and address unmet needs within our community. Before you go, we'd love to hear just a few more things.

124) Would you like to receive an email when the results of this survey are published?

- Yes
- No

125) Are you interested in attending the Fall 2022 Schizophrenia Patient-Focused Drug Development meeting in the Washington, DC area?

- Yes, and I'd be willing to serve as a panelist
- Yes, but I do not want a speaking role
- No

126) How did you first hear about this survey?

- Advocacy organization website: [Enter name]:
- Doctor or other healthcare provider
- Friend or family member
- Schizophrenia PFDD Meeting website
- Other Internet site or social media
- Flyer or other printed material
- Other (please describe):*

127) Would you like to receive future information about other research opportunities from the Schizophrenia and Psychosis Action Alliance and its partners?

- Yes
- No

128) If you are interested in receiving information from us in the future or indicated interest in the Patient-Focused Drug Development meeting, what is your preferred email address?

If you would like to attend the Schizophrenia Fall 2022 Patient-Focused Drug Development Meeting in the Washington, DC area live or via the live webcast, you can register [here](#). If you indicated interest in speaking on a panel, we will be in touch in the coming weeks.

Confirmation of Submission

Thank you for taking our survey. We've recorded your responses, and look forward to being able to share the results of this survey.

**We Are a Global Impact Organization
Moving Individuals, Families, and Policies
Forward to Improve and Save Lives**

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