



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

Summary of Report on the Externally-Led Patient-Focused Drug Development Meeting on Schizophrenia
February 2023

On Nov. 2, 2022, people living with schizophrenia and their caregivers gathered virtually to discuss what it's like to live with this serious brain disease and share their experiences with current drug treatments.

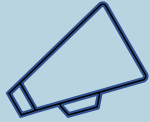
The meeting, ***“Reimagine Schizophrenia: Transforming How We Are Treated, Function and Thrive,”*** was part of the U.S. Food and Drug Administration’s Externally-Led Patient-Focused Drug Development (PFDD) initiative.

The meeting was co-hosted by:



HEALTHY MINDS • STRONG COMMUNITIES

Meeting Goals



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 treatments by providing insights on the treatment outcomes that matter most to people with schizophrenia and their caregivers, especially expected benefits and their willingness to tolerate specific risks.



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.

Key Meeting Themes



The impact of schizophrenia is often devastating and chronically disabling.



Multiple barriers stand in the way of successful treatment.



More effective treatments with fewer side effects are urgently needed.



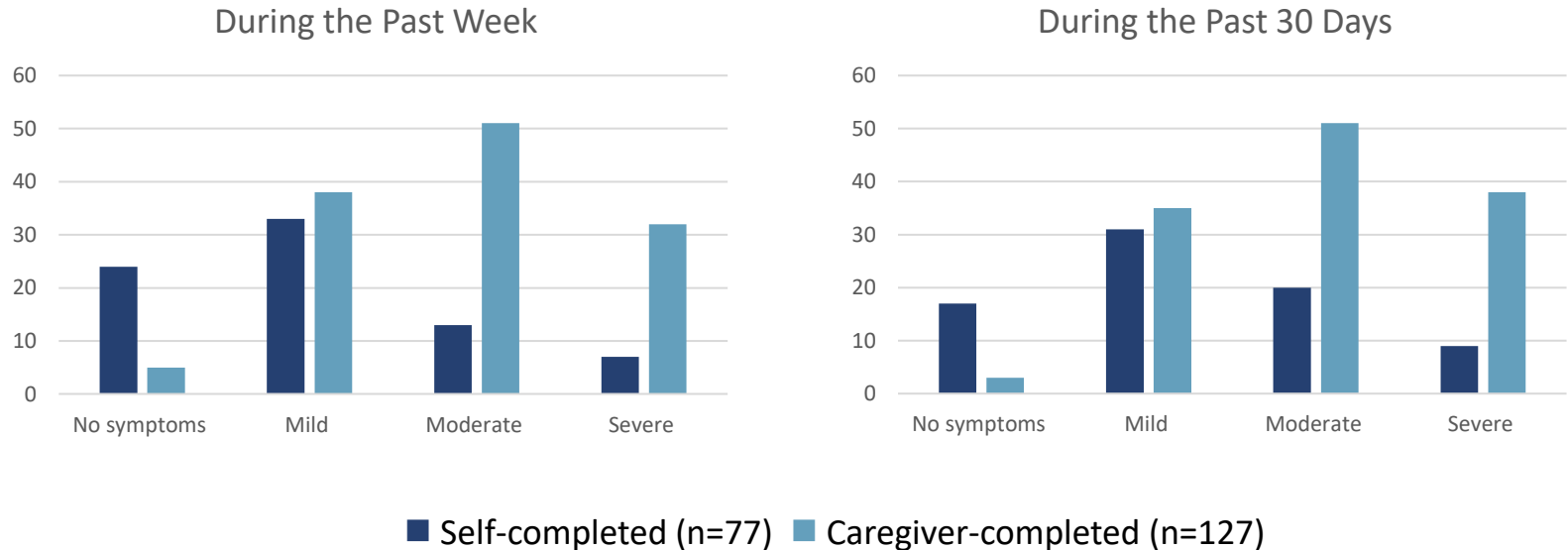
People with schizophrenia are not treated with urgency or understanding.



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

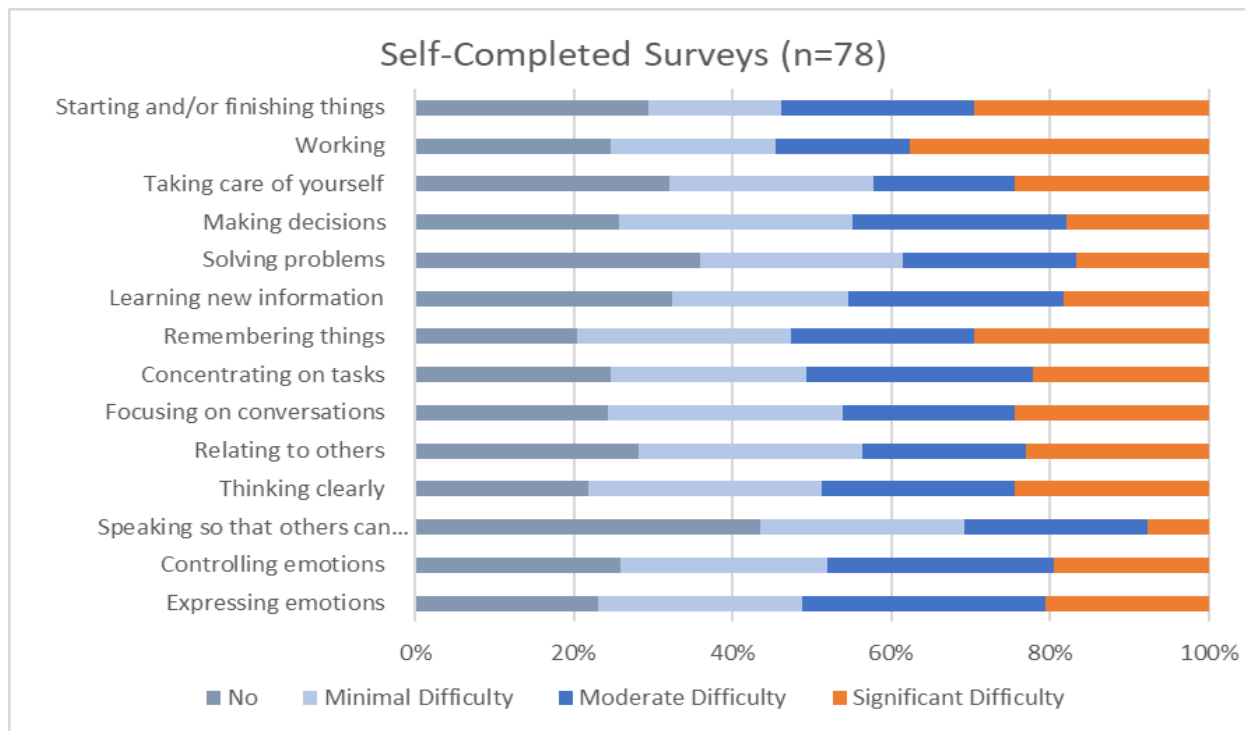
Despite current treatment, symptoms are frequent and have significant, negative impact on daily life

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



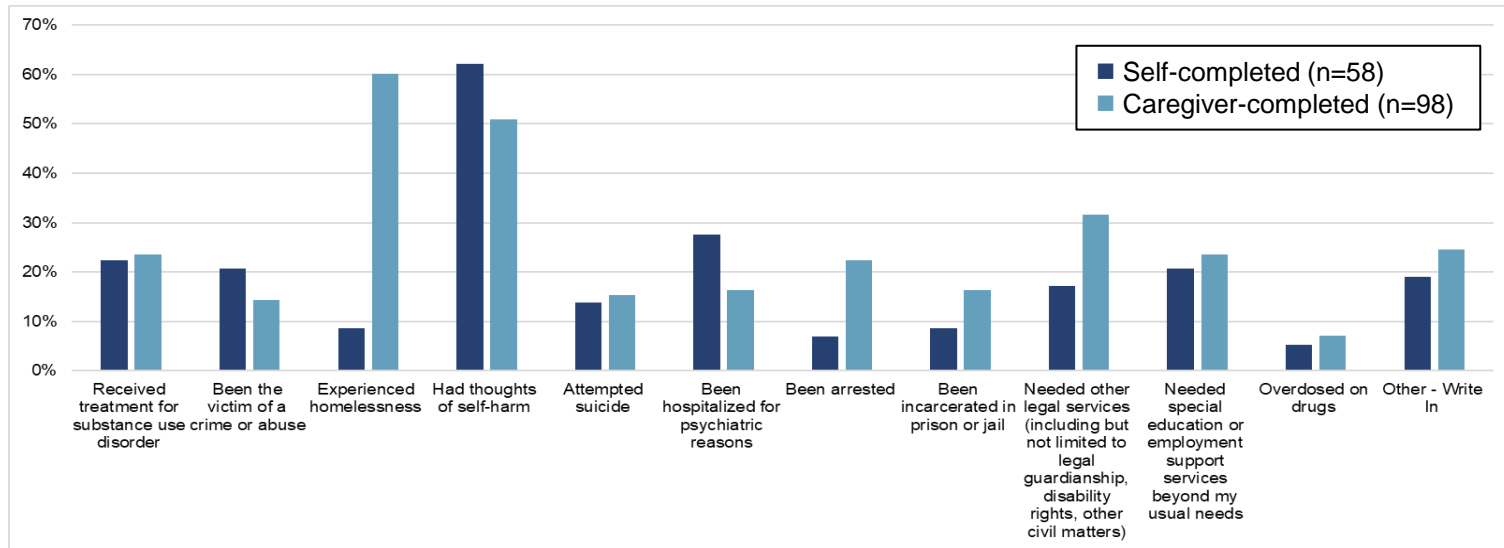
Cognitive dysfunction causes major life disruption

Meeting participants described how this brain deterioration created major difficulties with work, school and even just the activities of daily life.



Delusions and hallucinations can lead to violent urges

- Some panelists described how their delusions led them to commit self harm or acts of violence against others.
- Survey responses reflected many negative effects in the past 12 months:



Anosognosia often blocks treatment and leaves caregivers powerless

“Anosognosia has had the biggest impact on my son’s [illness]. He has no insight into his fixed delusions.”

Commenter describing her son’s illness

“His older sister has schizoaffective disorder. He began to develop symptoms similar to hers... and refused to acknowledge that there was anything wrong.”

Commenter describing how her son became unable to work, but refused treatment because of anosognosia

“He’s adamant that the hallucinations and delusions are real, not symptoms of a disease. Many of the psychotic medications have worked to reduce [those symptoms], but the belief of not being ill remains, and he quickly stops taking the prescription.”

Panelist describing why her son has struggled with medication adherence

Schizophrenia symptoms can trigger alcohol, drug use

“Eventually, I got divorced and almost lost everything.”

Panelist who self-medicated with alcohol

“It was a dark past of brokenness. And I lost my family because of homelessness.”

Panelist who used drugs and alcohol, experienced homelessness, had her children removed by court order and attempted suicide

“He was drinking very heavily and was very disorganized, and this was very much out of character for him... this drinking and disruptive behavior landed him in the brig.”

Panelist whose son was court martialled and discharged from his job as an Army medical specialist because of his schizophrenia symptoms

Schizophrenia can be a rollercoaster existence

"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."

"On his best days, [my son] 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."

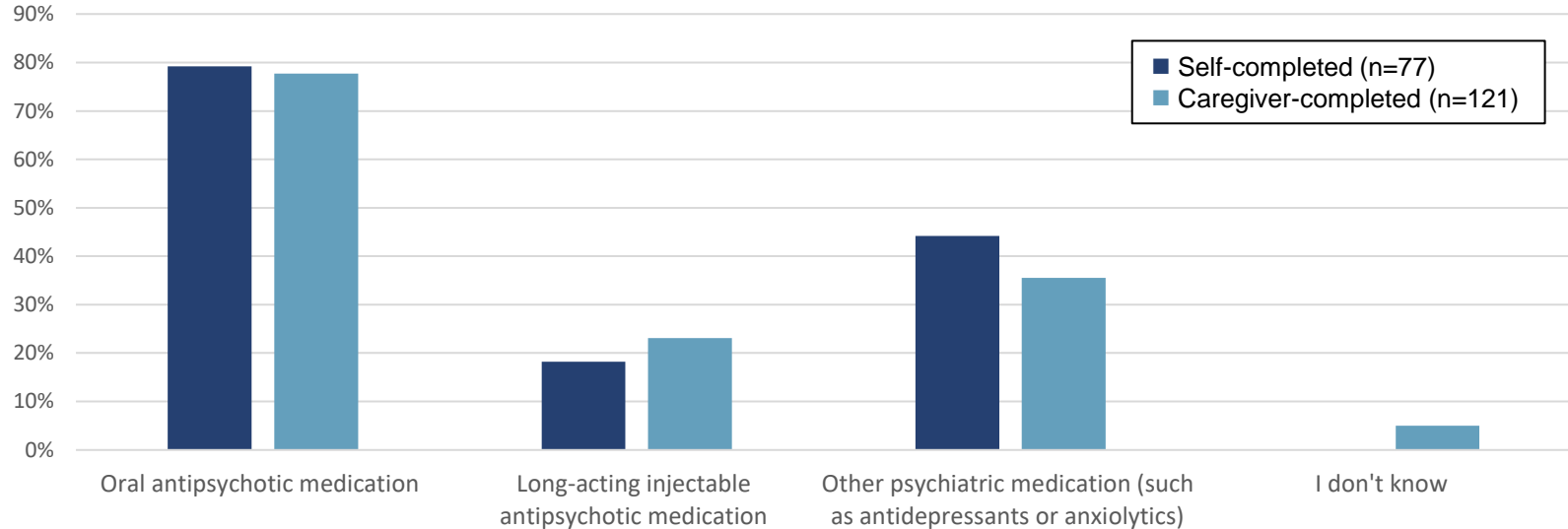




Meeting Topic 2:
Views on current and future treatment approaches

Many people take medications to manage the symptoms of their schizophrenia...

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



...But lack of efficacy, severe side effects often lead to switching or stopping treatment

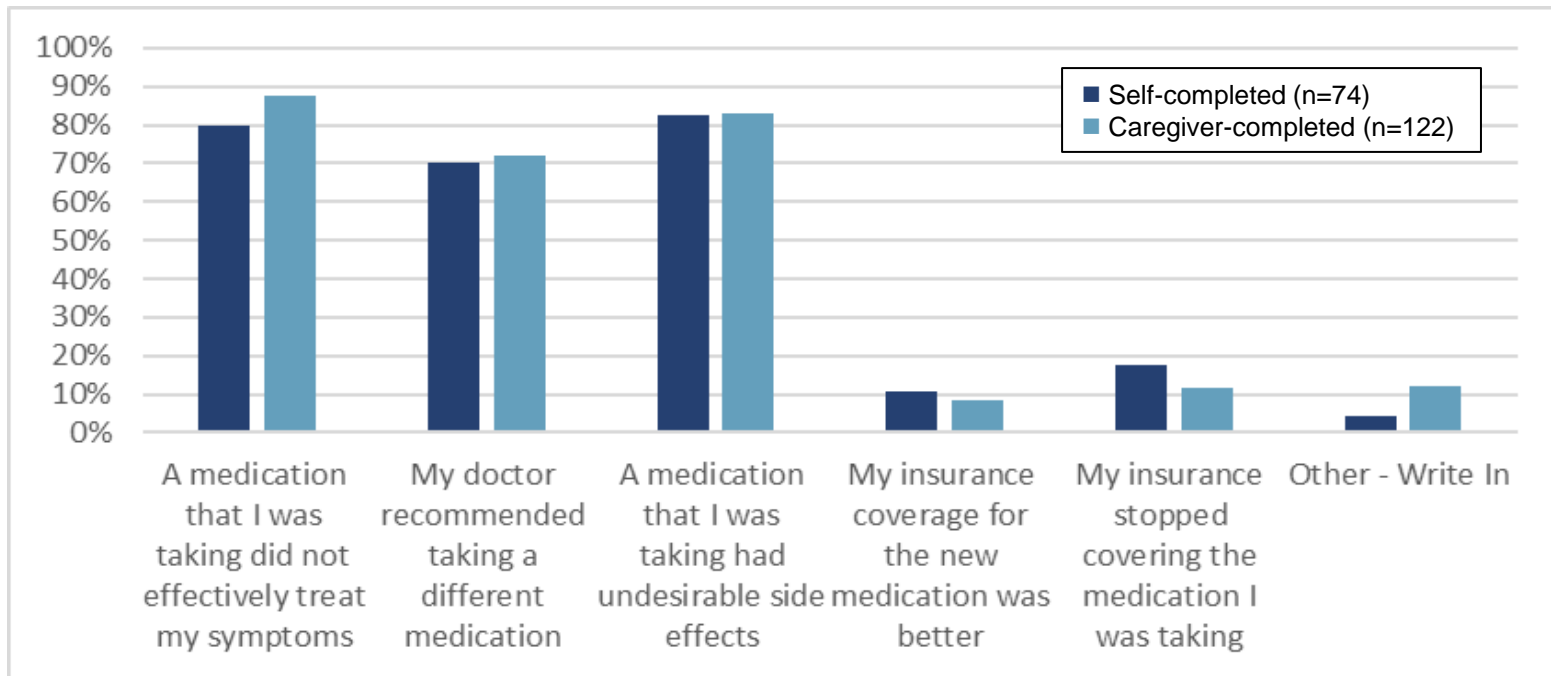
- The majority of survey respondents said they switched medications because treatments were ineffective against symptoms, caused serious side effects or their doctor recommended it.
- Many survey respondents and meeting participants described stopped their medicines for many reasons, including that the medication:
 - Did not treat symptoms effectively
 - Caused them to feel “flat”
 - Caused excessive weight gain

“I've never been on an antipsychotic medication that works for these delusions. I dream of being on one that works, so I don't have to live these nightmares, so I don't believe these delusions.”

“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.”

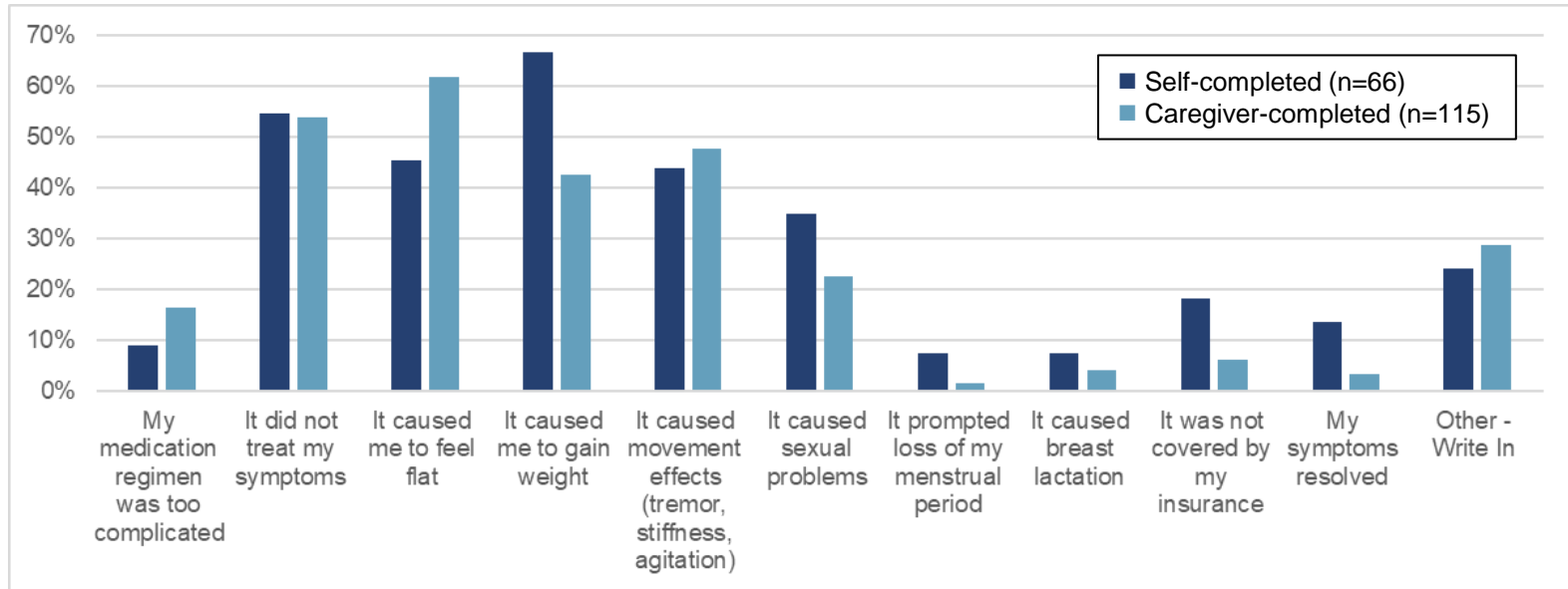
Majority of patients have switched medications

“Have you ever switched from one medication to another for the reasons below?”



Lack of efficacy, side effects cause many to stop treatment

“Have you ever quit taking a medication prescribed to treat your schizophrenia for any of the following reasons?”



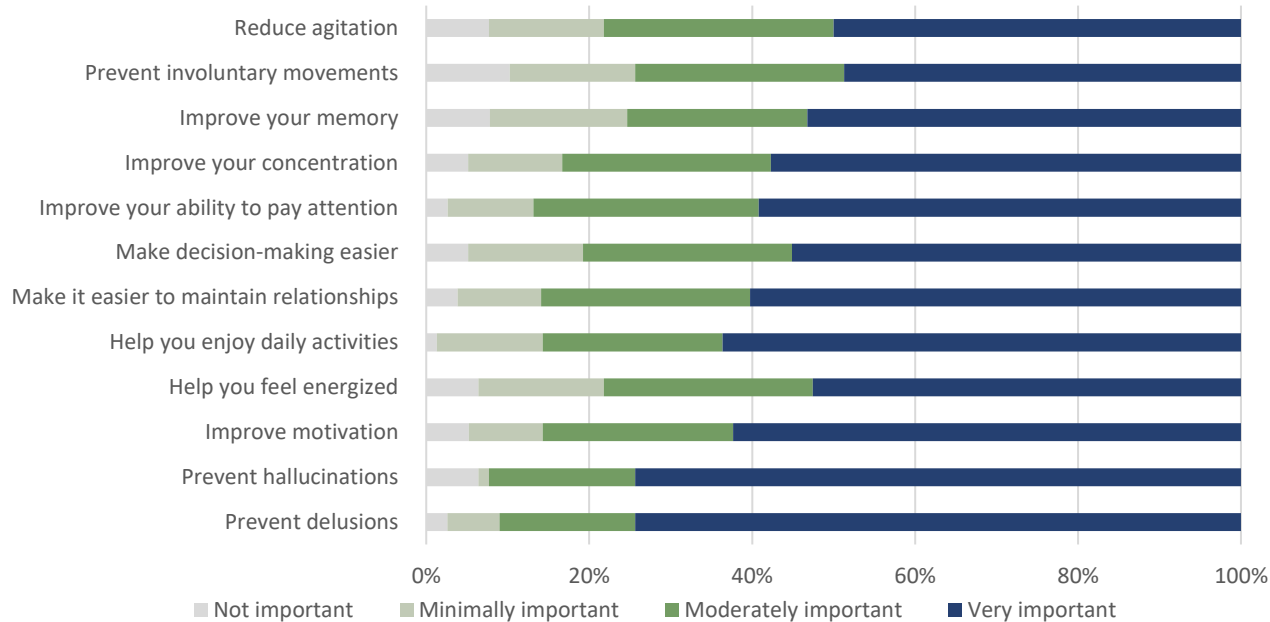
Clozapine works for many patients, but access is heavily restricted

“Since starting clozapine, I fulfilled all the blood work requirements for REMS. It has been a major commitment... **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.”

“None of the medications that 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. **Approximately three months after starting clozapine, [my son] kind of woke up and was able to read, able to study and eventually able to go back to college.**”

There is a desperate need for better treatments & outcomes

When thinking about new treatments for schizophrenia, how important is it that they... (self-respondents, n=78)



“With the right medication, the right doctors, the right therapists, psychiatrists and family and friends, we can be on the road to recovery.”

A call to action from people with schizophrenia



Many patients spend years trying multiple medications to find one that works for them — and **some have yet to find one.**



Existing therapies can cause significant side effects that lead people with schizophrenia to stop taking them — risking a return of severe disease symptoms.



People want new, better treatments that **more effectively treat their hallucinations, delusions & other disabling symptoms** — without severe side effects.



People who have found success with clozapine want fewer regulatory restrictions so that they can **more easily access treatment and avoid the anxiety – and danger – 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.

We thank our corporate sponsors, whose funding supported webcasting and consulting services for the meeting:

PLATINUM



GOLD



SILVER



BRONZE





Appendix

Background on pre-meeting survey

OBJECTIVE

Gain greater understanding of what it is like to live with schizophrenia, what individuals with schizophrenia want from drug treatments and to inform design of the EL-PFDD meeting.

DESIGN

- Combination of multiple choice, ranking and open-ended questions
- Phrasing tailored to audience
- Open Aug. 9-Sept. 26, 2022

TARGET AUDIENCES

- 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

TOPICS

- Severity of symptoms
- Effects of symptoms on daily living
- Medications used to treat symptoms
- Reasons for medication cessation and switching

Survey respondent characteristics

Respondent Characteristics	Self-Completed (n=78)	Caregiver-Completed (n=128)
Mean Age [Range]	45.4 [21,80]	32.8 [18,81]
Gender		
Male	47.4%	77.3%
Female	46.2%	20.3%
Non-binary, another identity, or prefer not to answer	6.4%	2.4%
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		2%
Ethnicity		
Hispanic, Latino, or of Spanish origin	8%	7%

Employment & Educational Status	Self-Completed (n=78)	Caregiver-Completed (n=128)
Employment Status		
Full-time	22%	4%
Part-time	22%	9%
Actively looking	6%	2%
Not employed	31%	84%
Retired	15%	1%
Prefer not to say	4%	0%
Educational Status		
Yes, full-time	4%	4%
Yes, part-time	13%	7%
No	83%	88%
Don't know		1%