



Clincierge



Amplifying Patient Voices in Rare Disease Trials

Understanding patient and caregiver experiences and how effective patient support strategies reduce barriers, increase retention, and improve outcomes in rare disease clinical trials.

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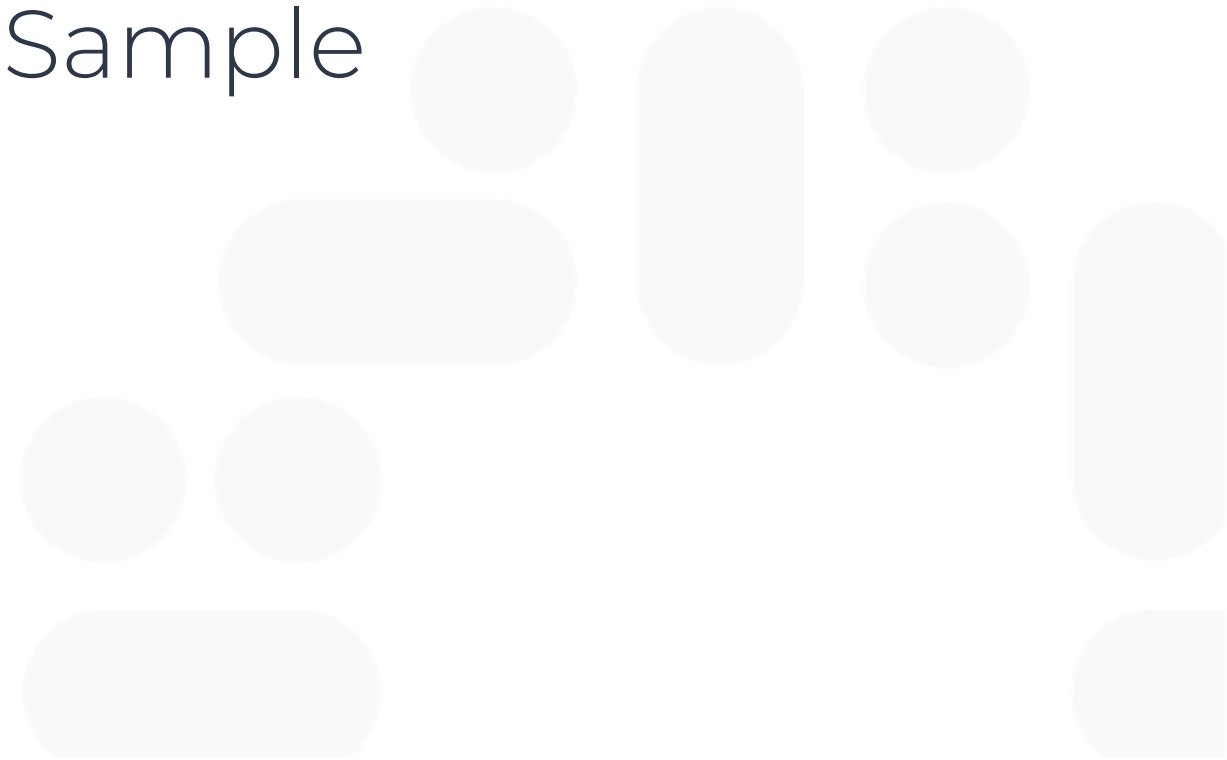
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SECTION 1

Background, Method, Sample



Background

Clinclerge recently conducted a qualitative study to explore the experiences of patients and caregivers through the process of traveling for clinical trials. By listening to these patients and caregivers, we gained a deeper and more nuanced understanding of the dimensions of their experiences.

Clinclerge subsequently conducted a quantitative study to further develop an understanding of the experiences of patients and caregivers in clinical trials and the impact participation barriers have on clinical trial outcomes.

Qualitative Methodology

- Participants in the rare disease space were recruited to participate in a qualitative, in-depth research study.
- Recruitment included an online questionnaire followed by a screening call with the research firm Insight and Measurement.
- Participants came from Rare Patient Voice, whose database includes patients and caregivers with 450+ indications. Their identities were anonymized in the research results.
- 24 Participants logged into an online platform for 30-minutes per day for 5 days to answer questions and engage in activities related to their trial experience. See Appendix A for the activity guide.
- Responses were collected in Summer 2021.

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- A photograph showing a caregiver in a white uniform assisting an elderly patient. The patient is wearing a grey hairnet and is using a metal walker. The caregiver is leaning in, providing support. The background is a plain, light-colored wall.
- Breast Cancer
 - Duchenne Muscular Dystrophy
 - Fibrodysplasia Ossificans Progressiva
 - Follicular Lymphoma
 - Hereditary Spastic Paraplegia
 - Huntington's Disease
 - Lung Cancer
 - Metastatic Breast Cancer
 - MPS II Hunter Syndrome
 - Multiple Myeloma
 - Multiple Sclerosis
 - Primary Hyperoxaluria Type 1
 - Rett Syndrome
 - Spinal Muscular Atrophy

Quantitative Methodology

- Insight and Measurement collected the data through an internet-administered survey.
- Patients and caregivers were recruited from Rare Patient Voice to participate in a quantitative survey.
- Survey invitations were sent to all 6,449 patients and caregivers in 22 rare disease or condition panels, with 856 valid responses.
- 117 Participants, 60 patients and 57 caregivers completed a 20-minute survey.
- All respondents were paid \$35 for completing the survey
- The study was divided into Part I and Part II, described next
- Responses were collected in Spring 2022

- Acute Myeloid Leukemia
- Addison's Disease
- Alpha 1 Antitrypsin Deficiency (A1AD)
- Amyotrophic Lateral Sclerosis
- Basal Cell Carcinoma
- Deletion Duplication Syndrome
- Desmoid Tumor
- Fragile X Syndrome
- Gaucher Disease
- Glioblastoma
- Hereditary Angioedema
- Human Growth Hormone Deficiency
- Microcephaly
- Muscular Dystrophy
- Neuroendocrine Cancer
- Pulmonary Arterial Hypertension
- Primary Immunodeficiency
- Pulmonary Arterial Hypertension
- "Feeding Tube Caregivers of children 0-17"
- RPV's "Feeding Tube Patients"
- RPV's "Wheelchair User" Panel
- Waldenstrom's Macroglobulinemia (WM, Lymphoplasmacytic Lymphoma)

Quantitative - Part I & Part II

Part I (n = 856)

- For Part I, we sent invitations to all 6,449 members of the panels of diseases
- The invitation was simply to take a 15-to-20-minute survey, without mentioning the topic
- This allowed us to use our “screener” to estimate such issues as the percent of patients and caregivers who have been asked to participate in clinical trials, the percent who have declined to participate in clinical trials, and so forth
- For this part of the project, we had 856 responses to the screener of the survey
- For Part I, we analyzed the screener of the survey, not data in the main body of the survey

Part II (n = 117)

- Part II was the primary objective of this project
- For Part II, which we will call the primary survey, we also added five days of recruiting where we asked specifically for patients and caregivers who have participated in clinical trials
- For this part of the study, we had 117 completed responses to the main body of the survey
- For Part II, we analyzed both the screener and the main body of the survey
- The key screening criteria were respondents had to be at least 18 years of age, have participated in a clinical trial in the past 4 years, and the clinical trial required them to travel by air or ground travel took at least 3 hours
- We received 117 qualified responses, 60 patients and 57 caregivers from 5/4/22 to 5/10/22

Institutional Review Board (IRB) Approval

To support plans to make the information from our quantitative study known to the healthcare community, we wrote a protocol and submitted it to an institutional review board (IRB), Advarra, for approval

On 4/27/22, we received approval and an “exempt determination” as the study was not invasive and met the requirements of the IRB

The exempt determination letter from the IRB is displayed in the Appendix C.



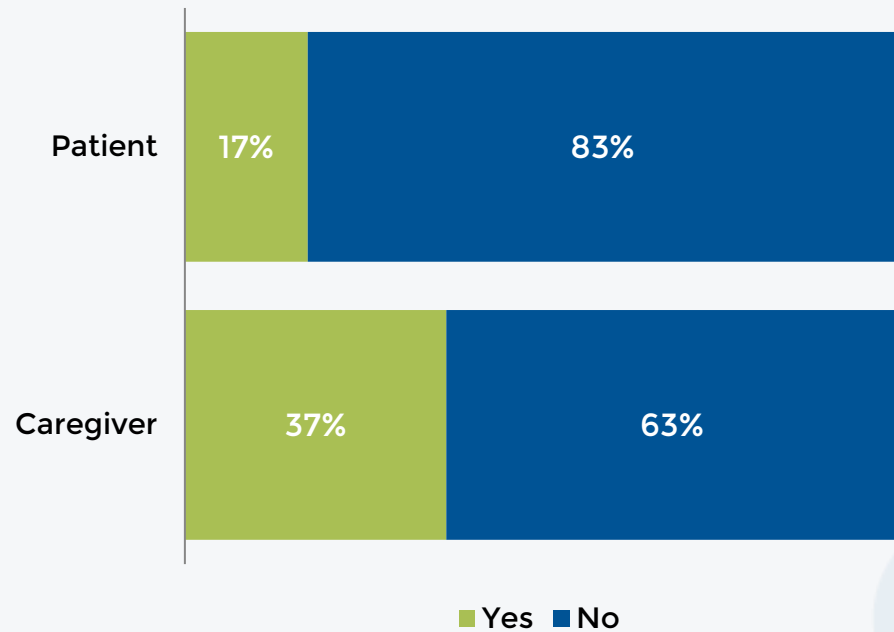


SECTION 2

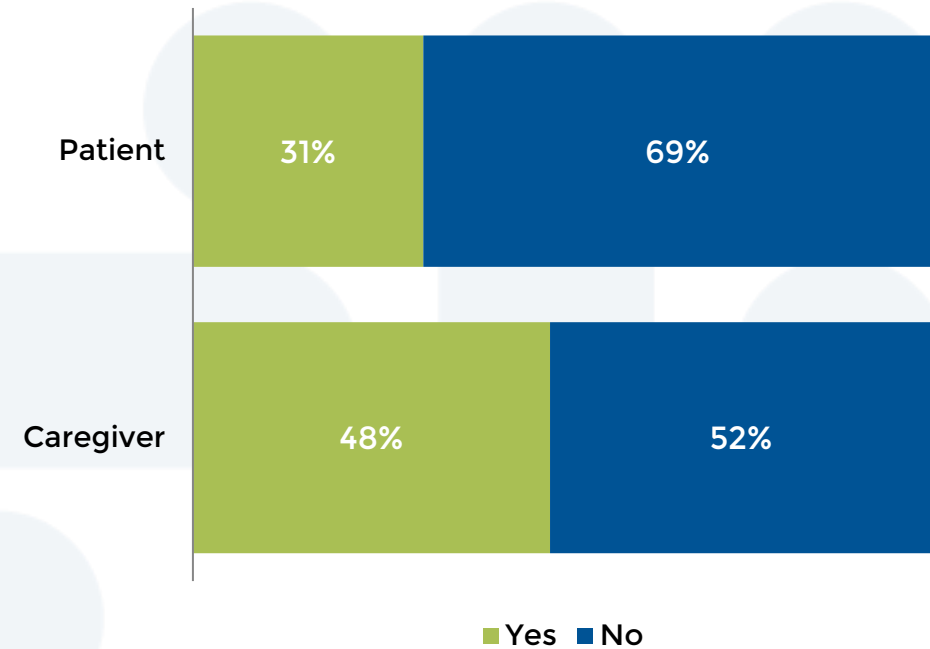
Part I & Part II: Clinical Trial Participation

Part I - Trial Participation

Are you currently participating in a clinical trial?



Were you participating in the clinical trial at any time during the Covid-19 pandemic?



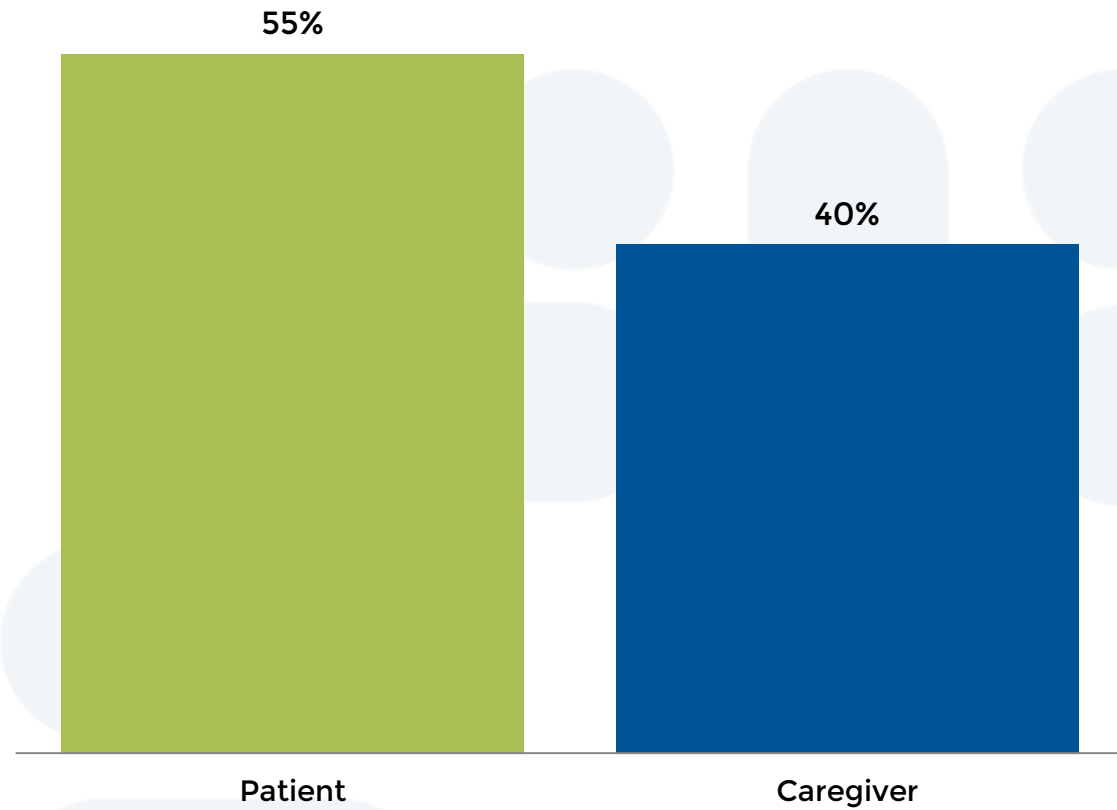
Patients: (n=632)

Caregivers: (n=224)



Part I - Trial Participation

Decided NOT to participate in a clinical trial?



Patient

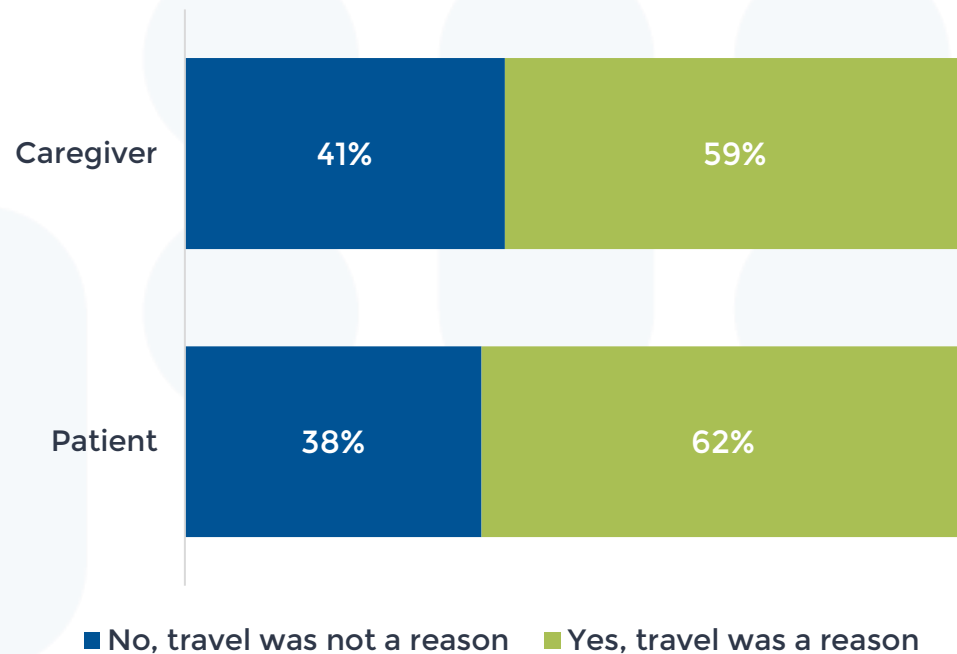
Caregiver

Patients: (n=632)

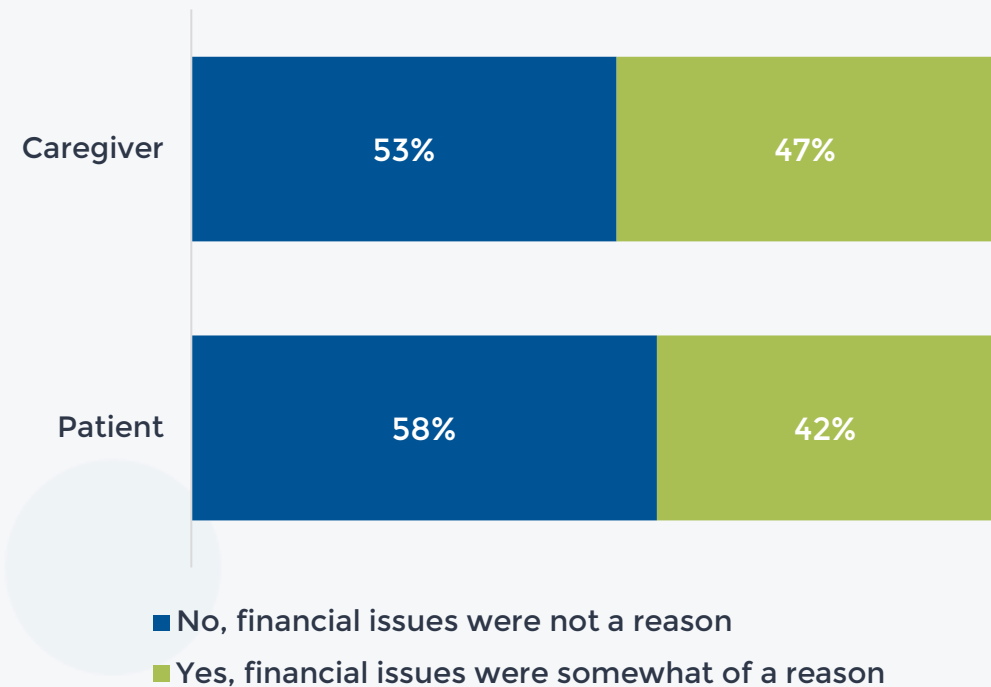
Caregivers: (n=224)

Part I - Trial Participation

Was TRAVEL a reason for deciding to NOT participate in one or more clinical trials?



Were FINANCIAL ISSUES a reason for deciding to NOT participate in one or more clinical trials?

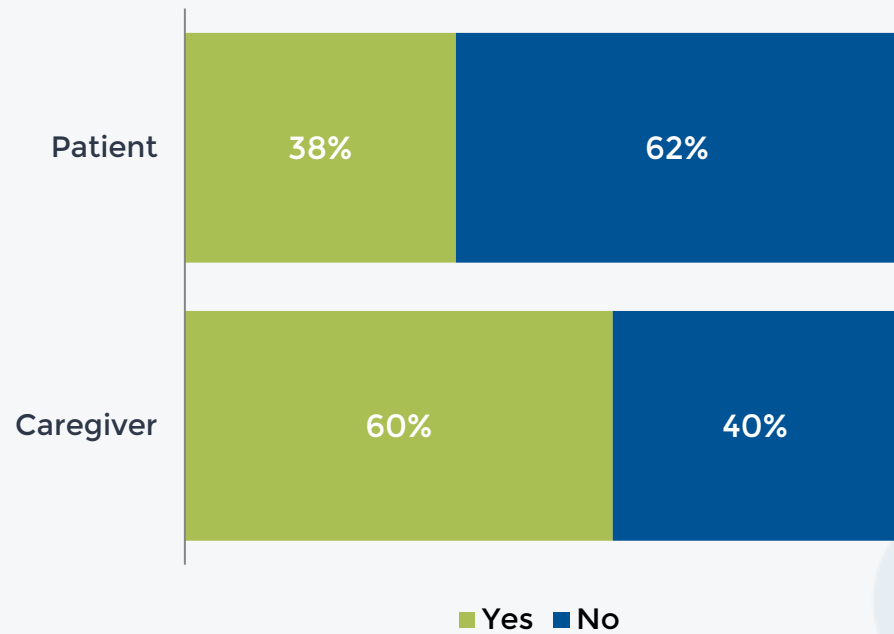


Patients: (n=632)

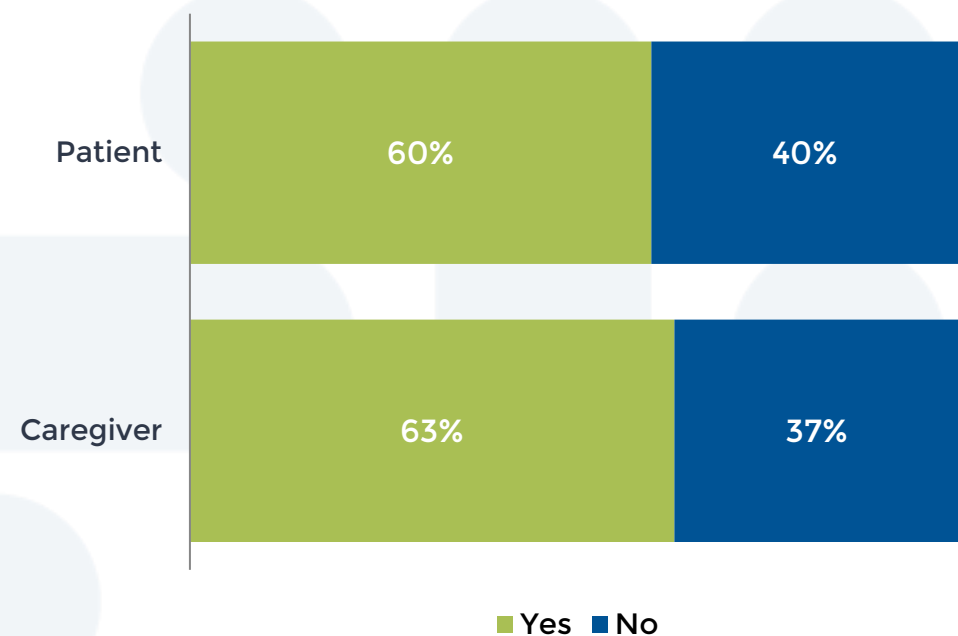
Caregivers: (n=224)

Part II - Trial Participation

Are you currently participating in a clinical trial?



Were you participating in the clinical trial at any time during the Covid-19 pandemic?

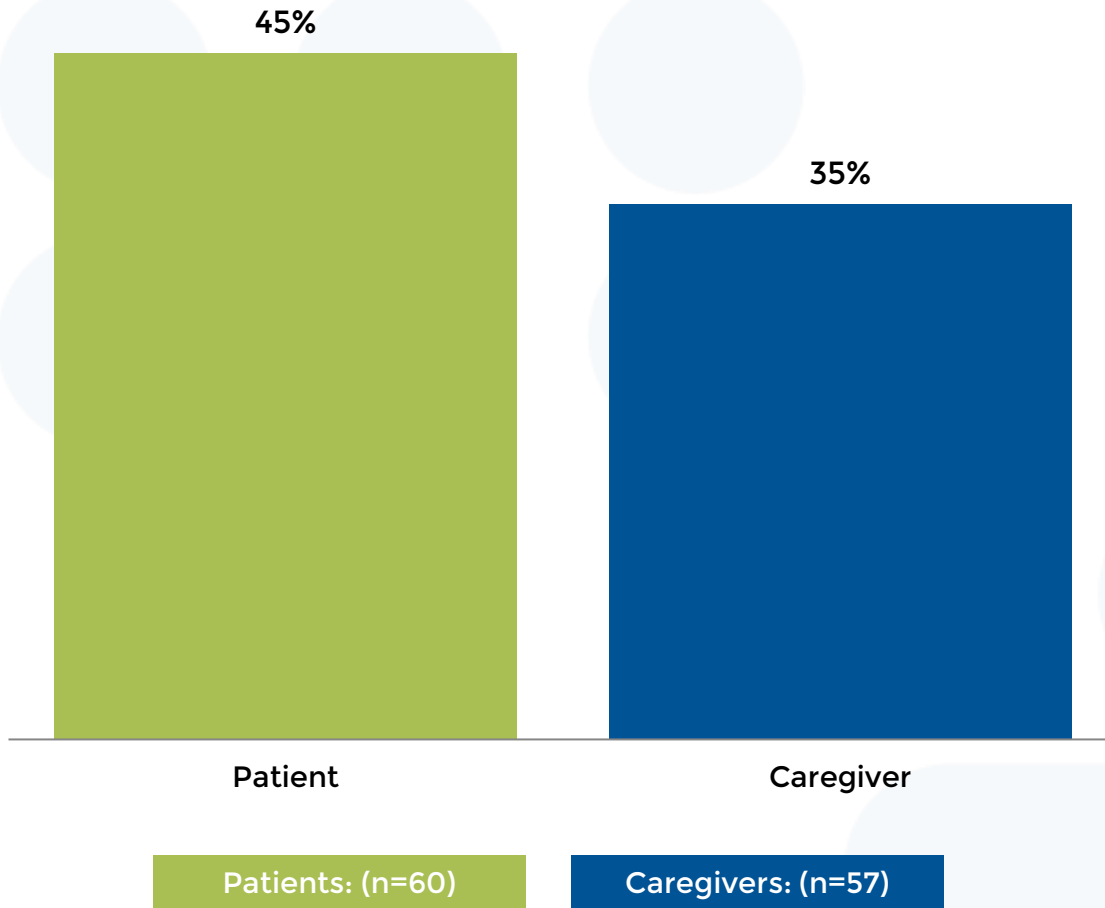


Patients: (n=60)

Caregivers: (n=57)

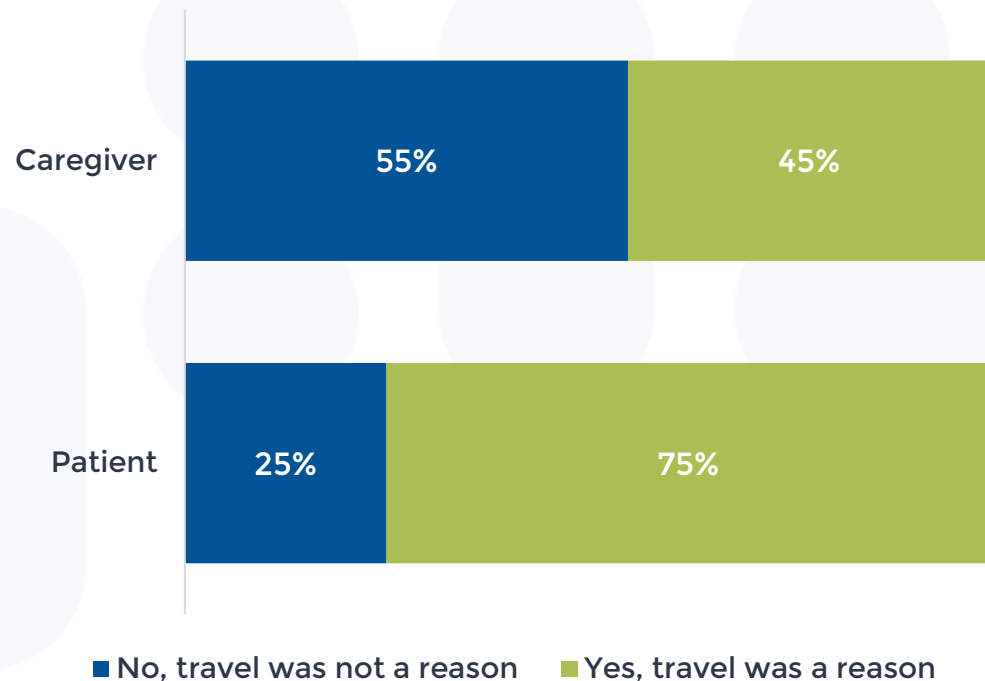
Part II - Trial Participation

Decided NOT to participate in a clinical trial?

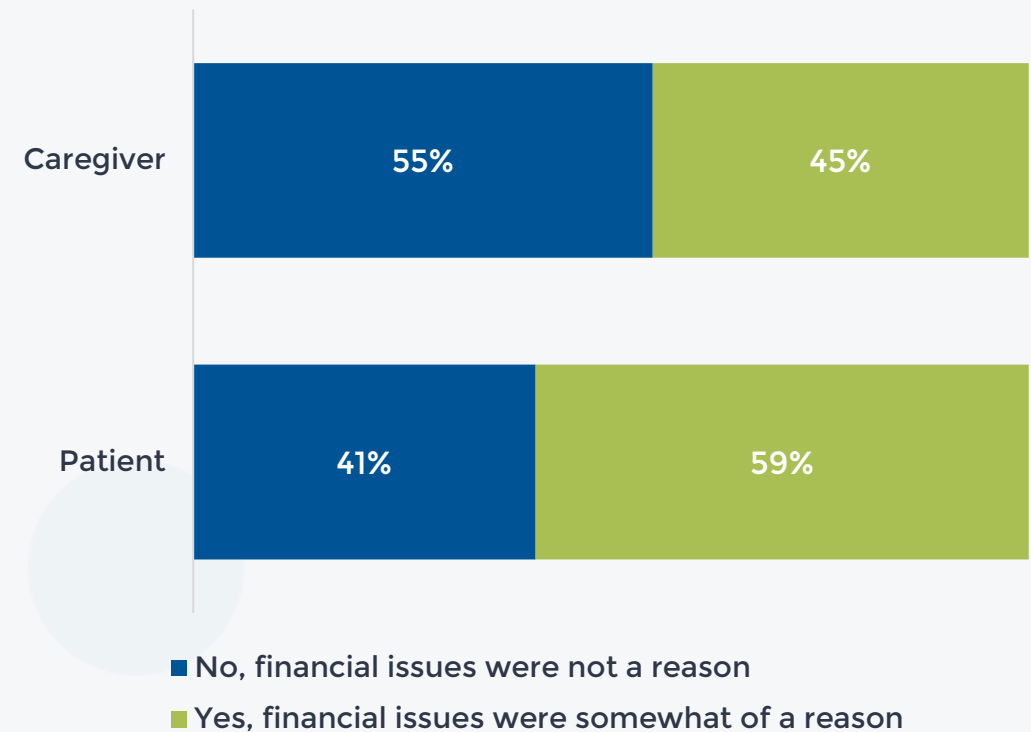


Part II - Trial Participation

Was TRAVEL a reason for deciding to NOT participate in one or more clinical trials?



Were FINANCIAL ISSUES a reason for deciding to NOT participate in one or more clinical trials?



Patients: (n=60)

Caregivers: (n=57)



SECTION 3

Understanding Emotional Barriers to Participation

Emotional Barriers

- Feeling overwhelmed by it all
- Determination to fight the disease
- Discomfort from travel & being away from home
- Anguish of watching loved one suffer
- Strain of being stretched so thin and feeling inadequate; exhaustion
- Uncertainty as to whether treatment is working
- Physically and emotionally draining



“subject”? I am not a freaking “subject”!!!

“#WordsMatter. Trial participants should NEVER be referred to as [subject] - we are people, not rats. We are participants, or volunteers, or my personal favorite, clinical trial heroes!”



Life of a special needs mom

“I’m sure every mom (or dad) feels like they have the weight of the world on their shoulders, but the shoulders of a special needs parent are even more weighed down. Are you making the right decision? Will we be able to add more to our already full plate? Will my child be able to handle the travel, meds, lab draws etc.?”

Emotions: When first learning about a clinical trial

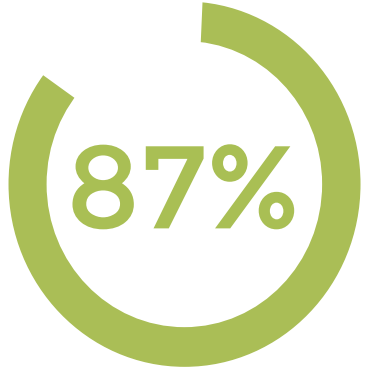
- Excitement/hope
- Hopes of slowing progression
- Hope to help others with this awful disease
- Worries/fears
- Drug/treatment ineffective
- Placebo
- Side effects
- Concerns
- Inconveniences
- Traveling long distances
- Disrupting life of family

“I didn't have any worries, just **excitement!** I already have [rare disease] and I need to be able to do everything in my power to help other people with it. I grew up going with my mom to her study appointments. I was familiar you with them and I was excited to continue on her path.”

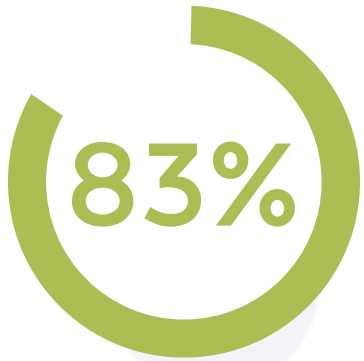
Worries: transportation issues. **Not having transportation for my [child] to and from school.**
Concerns: time involved or what if I wasn't able to finish because of illness.
Hopes: that it could help me with my disease and **slow down progression.**
Fears: that I would be **[disqualified]** with another illness/disability or be disqualified because I missed a session that was unavoidable.”

“I was worried about the **unknown** of course. What would the medicine do? **How would he handle all the travel and weekly infusions?** Side effects? I wasn't sure how we could make these weekly trips for so long. I hated the placebo length. My hope definitely outweighed my fears though. After talking with my [child] about the trial, I felt at ease. He wanted to help others even if it doesn't help himself. Without trials, we have no hope for a cure for his terminal disease. The data is so important, so we began our journey.”

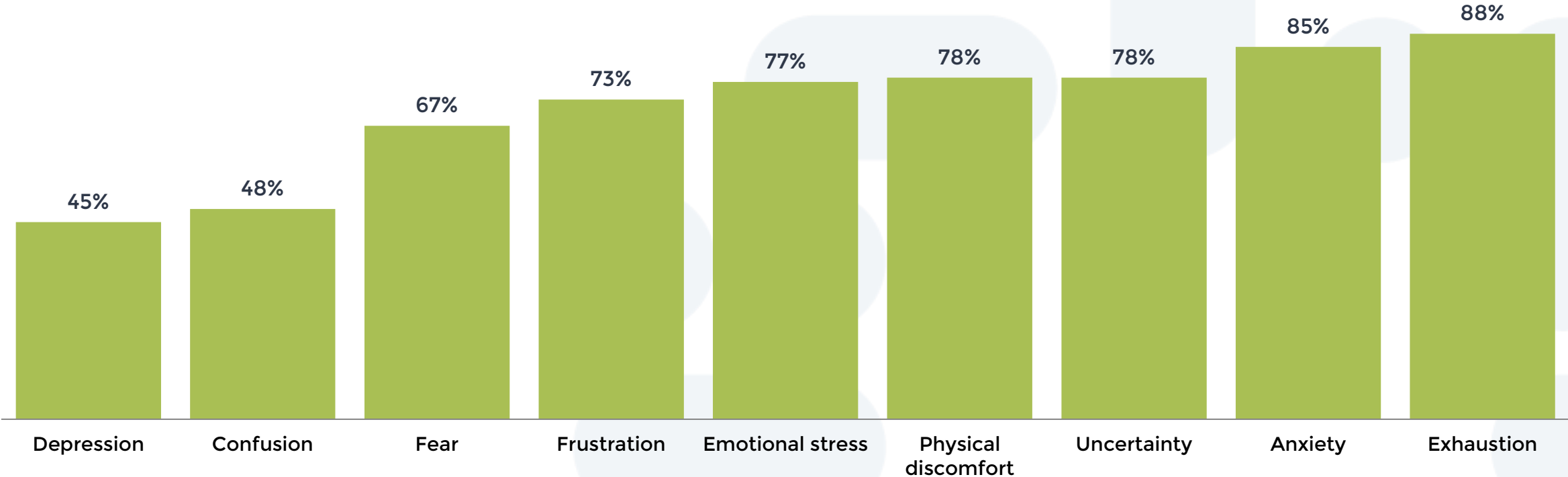
Patient Experience - Emotions



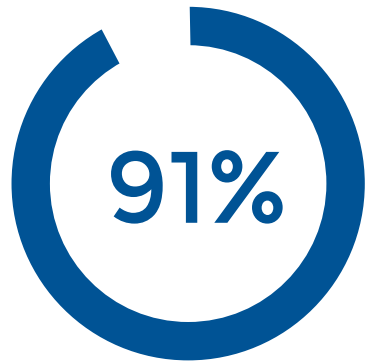
The majority of patients (87%) said participating in a trial was stressful for themselves or their family.



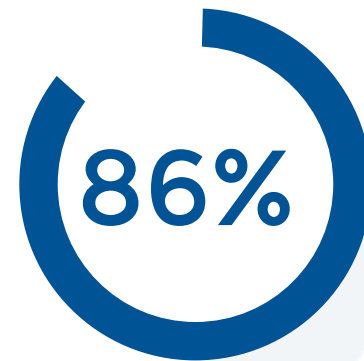
of patients reported feeling excitement related to participation in a trial, while also reporting the following emotions:



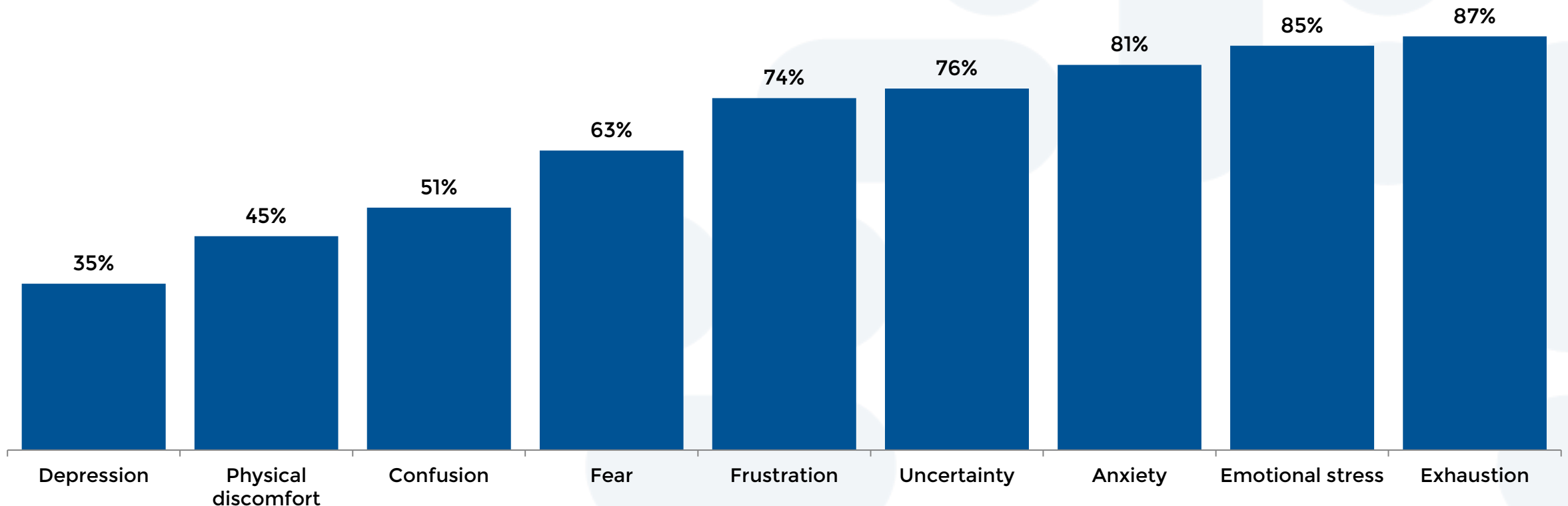
Caregiver Experience - Emotions



91% of caregivers said travel was stressful for themselves, their participating loved one, or the rest of their family.



86% of caregivers reported feeling excitement related to participation in a trial, while also reporting the following emotions:



Patient Experience - Spotlight

Patients expressed a wide range of emotions:

- Gratefulness to help themselves and help others
- Hope that the treatment would work, yet fear that it would not
- Uncertainty, apprehension, and anxiety about the treatment and the logistics
- Feeling overwhelmed by all the decisions and challenges around managing their home while away, kids and pets, finances, etc.
- Some expressed feeling determined and resolute to attack their disease



“We were concerned on whether we could afford going, **but we wanted to be a part of it so badly** we would have taken out loans and etc. to be a part. That’s how much this second trial we were a part of meant.

We **prayed** a LOT and asked for prayers and **hopefulness** from our friends and family to make us being in this trial possible. We asked for prayers for getting in, being able to afford the cost, finding people willing to keep our [child], that caregivers work would allow the time off.”



“I was **hopeful** the trial drug would help me, but also **worried** about what would happen if it didn’t.”



“I was **scared and anxious** all at the same time. I wasn't sure how I was going to make this work, who was going to take care of my dogs while I was gone, if I could find anyone to travel with me, if there would be any side effects, and if I was going to be hydrated enough for them to get me with the needle. I was just a big ball of anxiety, and I was in grad school (online classes) at the time, which I had to make sure I worked the schedule around my class schedule so I wouldn't miss classes. This image represents the stress/worry I felt inside while trying to figure everything out.”

Caregiver Experience - Spotlight

Caregivers, like patients, also expressed a range of emotions:

- Anguish over pain, suffering, and possible or eventual loss of life of their loved one
- Resolute and determination to fight for my child
- Hopefulness and prayer
- Scared, devastated, along
- Togetherness with the family
- Helpless
- Anxiety about the challenges of traveling and staying somewhere new



“It’s emotional to me because without a cure for my [child’s] disease, he will slowly lose the ability to hug me and I live for those hugs....He is my only [child], I would travel every day by foot, plane, train or automobile if it meant I could cure him from this awful disease. I cannot imagine my life without him, so the trial gives me hope. I need that in order to get out of bed in the mornings for not only my [child] but for the others affected by this as well. In other words, distance did not matter to me at all, I was **determined** to make this trial work no matter what I had to do, and I was also prepared for the heartbreak that may come along during this journey as well.”



“I am a **list maker**. When I had to think about all of the changes and decisions and preparation that would be involved in the clinical trial, my brain first tried to categorize it all and make sense of it and there was just too much. No one gave me a framework for what decisions needed to be made, what the options were, and even what factors needed to be considered. I had to sit down and look at every single area of our life, because every area would be affected, and figure out what needed to be done to make it work. **Financial, emotional, caregiving, strategic, relational, educational, future planning, spiritual, self-care, parenting, other resources** - all of these areas needed shifting and decisions.”

What was most stressful about travel?

HOME LIFE:

"The stress of making sure everything is taken care of at home, scheduling so that my husband can come help me and the worry of all that happens while traveling."

ADA:

"Worrying about my scooter making it through all flights, or a wheelchair being there and ready if I didn't bring my scooter. Worrying about accessible bathrooms being everywhere. Worrying about finding an Uber or similar at the airport that can fit the scooter..."

LOCAL SUPPORT:

"Not having a person in our time zone (country) to speak with when there are issues and the language barrier."

TRAVEL:

"Flying was the most difficult - getting on/off the plane with a disabled child. Catching flights late at night was hard, then finding a ride home was difficult...(plus) the uncertainty of how I was getting to the trial site...taxi? Uber? walk?"

LOGISTICS:

"The most difficult aspect of the clinical trial was planning the necessary travel and logistics with scheduling the visit, arranging flights, hotel accommodations, etc. for the trip. There is a lot of planning that goes into coordinating a clinical trial visit, it was a lot of work for me as a patient..."

CHILDCARE:

"Along with my child that's in the clinic trial, I also have two other young children. I've had difficulty in the past with getting their travel covered. It's hard to stay in a clinical trial with travel when travel isn't covered for my other kids."



SECTION 4

Exploring Logistical Challenges to Participation

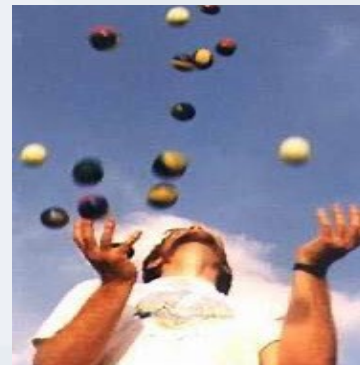
Logistical Challenges

- Travel delays
- Travel challenging depending on disabilities
- Locating ADA compliant hotels
- Inability to sit for long periods of time
- Unreliable car service
- Medications, meals and snacks
- Managing the household, kids, pets
- Coordinating help with family members
- Paperwork for reimbursements



How much time will it take?

“Will I be late for the trial? Should I drive another way? Should I leave 4 or 5 hours before I need to be there? How long will the trial take this time, and will the investigator and medical students not show up on time and I will have to wait another 1-2 hours before we begin? Will it be cancelled when I get there after I spent all that time driving?”



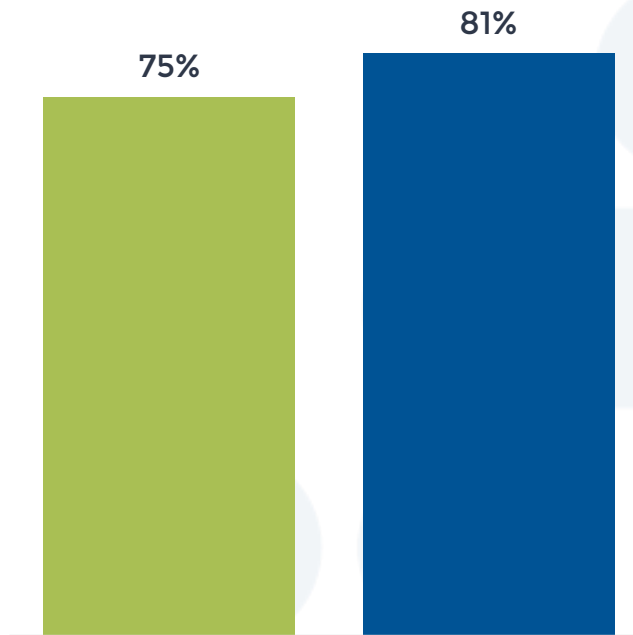
All the balls in the air

“All of the balls in the air and I'm juggling them or at least attempting too. each one represents a single thing I'm responsible for. Drop one and they all fall.”



Travel Experience

Trip included overnight stay:

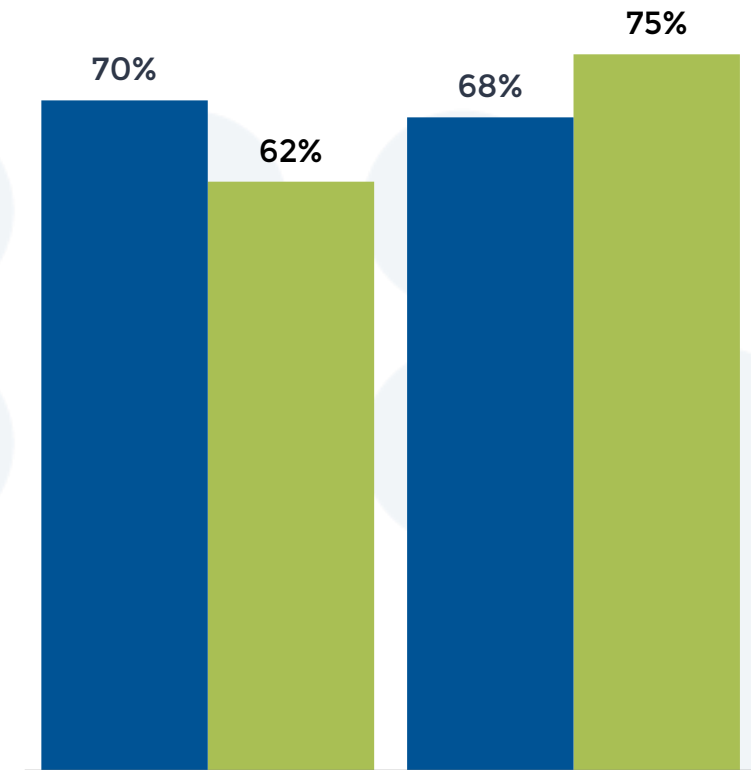


Patient

Caregiver

■ Patient ■ Caregiver

How did you travel?



Airplane

Car/train

■ Patient ■ Caregiver

Patients: (n=60)

Caregivers: (n=57)

How did you prepare for a site visit?

PATIENTS:

- Many start well ahead of time for travel and logistics
- Travel challenging depending on disabilities
 - Wheelchair access
 - Inability to sit for long periods of time
 - Direct flights best
 - Car service was sometimes unreliable
- Packing involves considerations of weather, possible delays getting back, making sure have all medications, snacks, etc.
- Timing is key - get there with time to spare, get back with time to decompress
- Coordinate everything with work schedule and schedule of children
- Some said they wished the trial site was closer to their home

CAREGIVERS:

- The journey begins with finding a trial for their loved one
- Planning begins weeks/months ahead of time
- Coordinating with other kids, spouse, work, other relatives
 - Adjusting schedules for both parents
 - Coordinating with schools
 - Coordinating for special needs children
- Travel and hotel
 - How to get there - drive or fly?
 - Where to stay, how close to the site?
- Packing
 - Prep for different weather at trial site
 - Packing all medications and equipment
 - Some need to pack for a service animal

Site Visit Preparation - Insights

“Most visits were **planned in advance**, which would typically start 2-5 months before the trip. I would coordinate with the site coordinator on when to schedule my visit (I had about a 3-month window for each planned visit). Once we settled on a date, she would contact the travel agent who would then work with me on setting up rides to/from the airport, flights, hotels, and rental car if needed.”

“A couple visits were planned within the matter of a week- **I'd have to get to the site within a couple days of a flare starting-** but those were planned much the same- just quicker / less options. After these visits I'd have to get back to the site in 50-60 days, but we started planning that the week after the trip.”

“Since I'm more of a control freak, I would often send the travel agent flight preferences & hotel preferences. My mom also helped a lot in the planning process (she would handle rental car, mostly). We tried to always do direct flights.”

“Also, **I would be expected in [study site city] the night before my visit. I'd have a one-day visit. Rest/ recover day, fly back on the 3rd (sometimes 4th) day.**”

“Our clinical trial visits are usually once every three months, and typically spend 2-3 days. **Once we get our next date, which usually about 6-8 weeks ahead of time, we start to talk about planning for the trip...** I also need off from work, and we need to cancel or reschedule [patient's] daily PT, OT, and speech therapy appointments. We also need to let [patient's] nurses not to come that day. We typically see it as too much of a burden to expect them to travel with us to the city.”

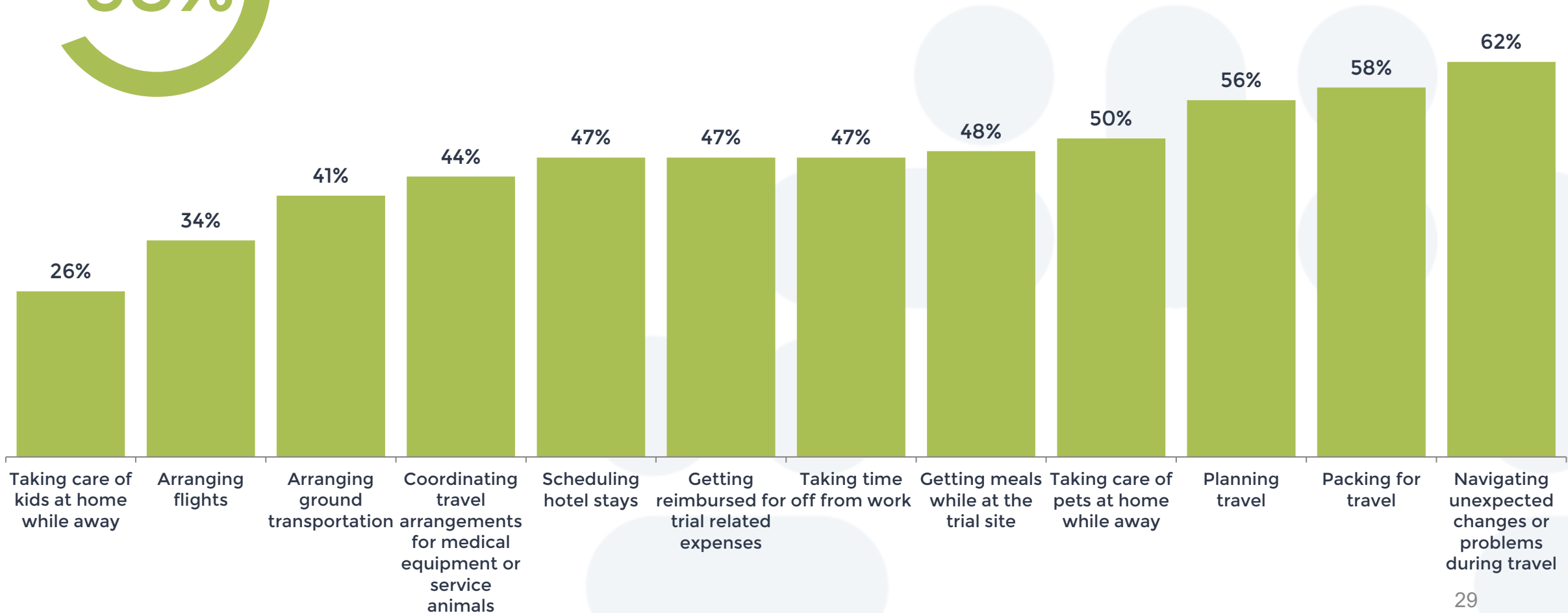
“Several weeks before a visit, I would have to **arrange for childcare for my other children**, putting together their schedules, informing their schools/activities/etc., doing medical authorizations for them in case they needed care while I was gone (in the event someone other than their father was staying with them, which was common). Even before that, **I would have researched travel arrangements before I called the travel agent** for the trial because I wanted the best arrangements for our schedule. **Additional preparation was usually in the three days before a visit - planning a reward system for my [child],** packing, pre-loading with my [child], buying snacks and rewards for the plane and trip, checking in with caregivers and anything on the schedule.”

“I would reach out to our **disease community** to see if any other families would be in the area or at the hospital the same time, we were so we could possibly get together.”

Patient Experience - Logistics

68%

of patients said traveling to the site was difficult
Reasons for the difficulty include:



Patient Experience - Challenges

32%

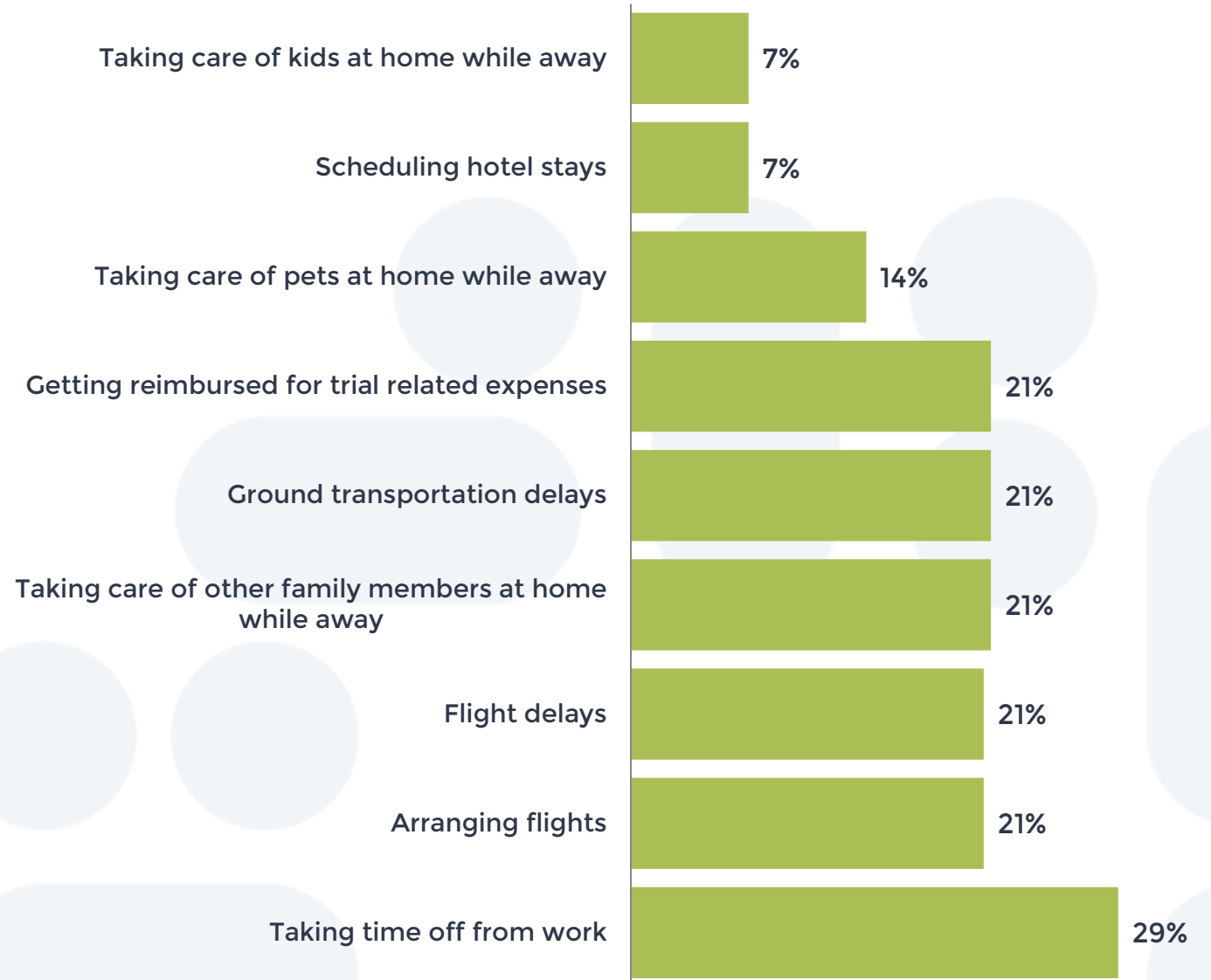
of patients considered dropping out of a trial

95%

said the travel related to participating was the primary reason for considering dropping out

23%

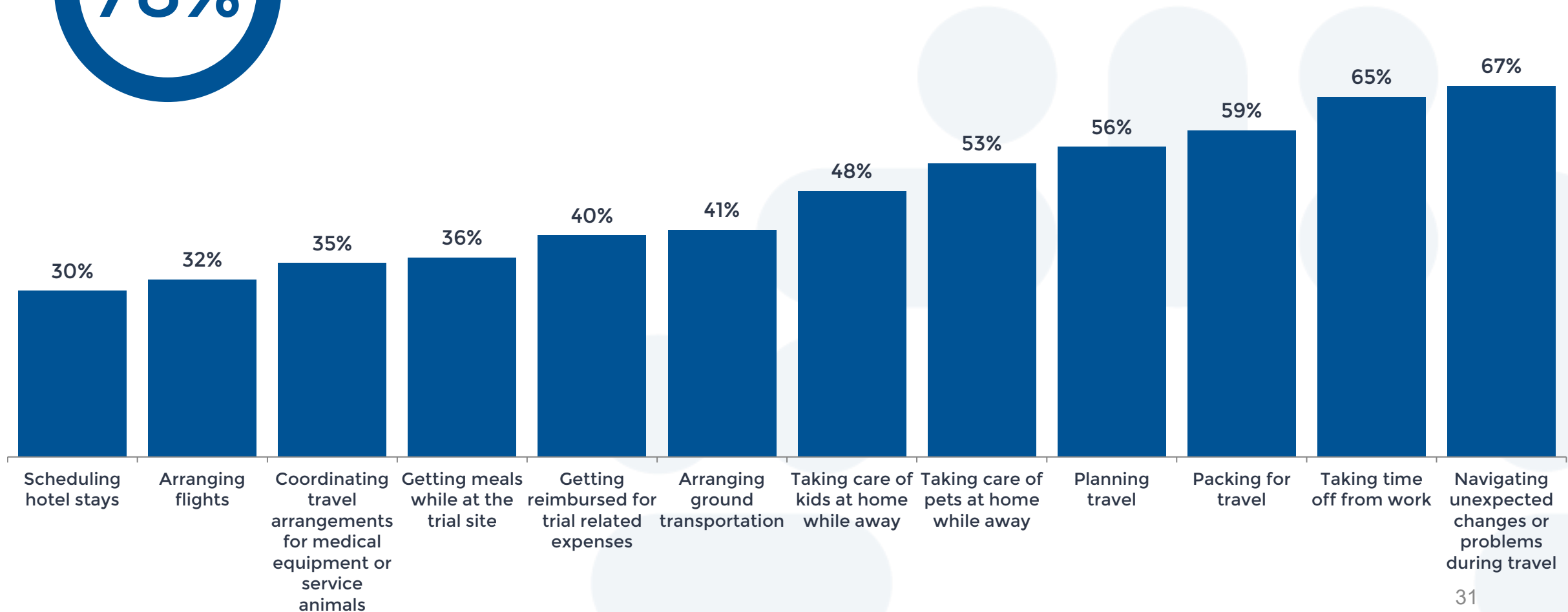
reported having missed study visits due to:



Caregiver Experience - Logistics

78%

of caregivers said traveling to the site was difficult
Reasons for the difficulty include:



Caregiver Experience - Challenges

30%

of caregivers thought about dropping out of the trial

94%

said the travel related to participating was the primary reason for considering dropping out

11%

reported having missed study visits due to:

Getting meals while at the trial site

17%

Taking time off from work

17%

Ground transportation delays

17%

Concerns about Covid-19

33%

Flight delays

33%

Logistical Challenges - Insights

“**Financial issues** are definitely the hardest thing - it's really good when they reimburse you for your time. The **family having to take that time off has been the hardest thing** to coordinate. thankfully between the three of them in the one that stays at the house to take care of everything at home for the dogs and the animals and my [child] still in school. coordinating that stuff with her brother an hour and a half away.”

“**Relocation,** setting up in another state and the health insurance changes to get the care and medications I needed not related directly to the trial.

“**Meals can be tricky.** I bring a small cooler or lunch tote with me, but usually, I just rely on protein bars and water since I have to eat in my car (parked of course) and need to eat something fast that does not need a lot of preparation and not heat sensitive.”

“**The physical and mental discomfort of some of the procedures.** I also had a long-term [medication] regimen that was difficult. Being poked and prodded for a long time can wear you down.”

“The **travel itself is the most difficult and unpleasant** aspect of my clinical trial experience.”

“The most difficult thing was to **keep things running smoothly at home** while you were away and trying to focus on the needs of the trial. Having children at home too - in school, activities, and otherwise missing their parent and sibling was hard emotionally, but also, you had to check in with caregivers and they would be calling you while you were at the hospital, and it was difficult to coordinate almost two separate lives.”

“The **exhaustion** on my end and having to wake him up so early for flights. Watching him cry during bloodwork or sleep during an infusion because he is so sleepy. Seeing all of the medical equipment was hard as well. **The energy and unknown** (we were in a 96-week possible placebo) after the 96 weeks were up, he would begin the medicine in the trial. Not knowing his data has been extremely hard as well.”

Patient Experience

53%

of patients say the most difficult studies included travel by air

50%

of patients said a company assisted them with travel

63%

of patients were satisfied with the transportation support they received

80%

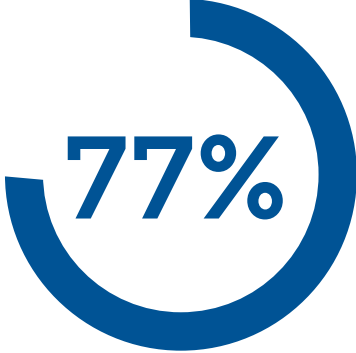
of patients said having patient support services helped them enroll and stay in the trial



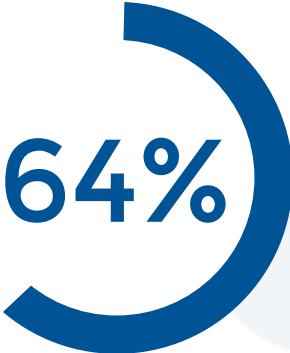
Caregiver Experience



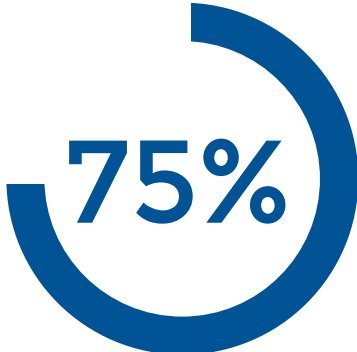
of caregivers say the most difficult trials included air travel



of caregivers had a company that provided travel support



of caregivers were satisfied with their travel support service provider



of caregivers said having such support services affected their ability to participate in the trial



Impact of COVID-19 on Participation



40%

of respondents said they participated in a clinical trial involving travel during the COVID-19 pandemic

“Before vaccines, COVID-19 made it a lot more stressful to go to a hospital with our son, as he is very vulnerable to respiratory illness...The main issue now is that only one parent is allowed to attend with my son. As he getting larger, it can be a strain to handle him physically throughout the day, while also keeping him entertained. He can't be left alone, so it's difficult to get food or anything like that.”

“[COVID-19] made travel more difficult practically and emotionally. We had to cancel a couple of visits or have tests done from home and sent to the labs. On the times I did travel it was more difficult to get food and was a very isolated experience having to camp out in your hotel room. I used to have opportunities to unwind or decompress from the day of tests, so it made it harder mentally.”

What was most stressful about travel?

HOME LIFE:

“The stress of making sure everything is taken care of at home, scheduling so that my husband can come help me and the worry of all that happens while traveling.”

ADA:

“Worrying about my scooter making it through all flights, or a wheelchair being there and ready if I didn’t bring my scooter. Worrying about accessible bathrooms being everywhere. Worrying about finding an Uber or similar at the airport that can fit the scooter...”

LOCAL SUPPORT:

“Not having a person in our time zone (country) to speak with when there are issues and the language barrier.”

TRAVEL:

“1. Flying was the most difficult. Getting on/off the plane with a disabled child was difficult. Catching flights late at night was hard as well and then finding a ride home was difficult. 2. Another thing was the uncertainty of how I was getting to the trial site...taxi? Uber? walk?”

LOGISTICS:

“The most difficult aspect of the clinical trial was planning the necessary travel and logistics with scheduling the visit, arranging flights, hotel accommodations, etc. for the trip. There is a lot of planning that goes into coordinating a clinical trial visit, it was a lot of work for me as a patient...”

CHILDCARE:

“Along with my child that's in the clinic trial, I also have two other young children. I've had difficulty in the past with getting their travel covered. It's hard to stay in a clinical trial with travel when travel isn't covered for my other kids.”

SECTION 5



Financial Burdens of Trial Participation



Insights into Financial Burdens

- Getting reimbursed was difficult for most
- Reimbursement took from a few days to several weeks
- Few had an online portal
- Prepaid debit cards were most common
- A few received checks

“I took pictures of my receipts from the meals and other expenses that were allowed. I submitted the photos and a form that was required which itemized each expense. There was a daily dollar limit that we had to make sure we didn't go over. Once we submitted the receipts it was a few days before the money was transferred. The only receipts that were accepted were ones that had itemized lists of what was ordered/purchased. This was sometimes problematic when buying food from places that did not supply us with itemized receipts. It would have been better if we could have some leniency regarding this when not going over the daily dollar amount.”

“The process was simpler when we could just take the money off of the card at the bank. But it was still fairly simple.”

“It was not simple, we had to keep all our receipts and track everything and scan it in. There were many times where we weren't given the right amount of money back. I can't think of a better secure way to make it easier. I guess if we could upload the receipts into a portal and see the amounts, and how they add up, and then see that each item was covered. Instead, we just see a total and it's broken out different each time so its hard to track.”

“We got hotel room through state funding as our child was qualified for Medicaid but all other expenses like gas, food, medical supplies was out of pocket expenses and we did not get any coverage for that.”

Impact of Financial Issues on Participation



of patients said financial burdens were a big reason to not participate in a trial



of patients said they received reimbursements for trial-related expenses

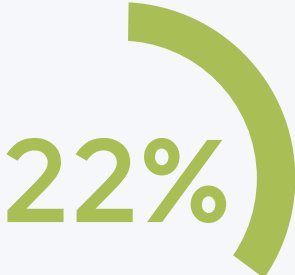


of patients said receiving reimbursements for trial-related expenses made it easier to participate

Patient Experience - Payments

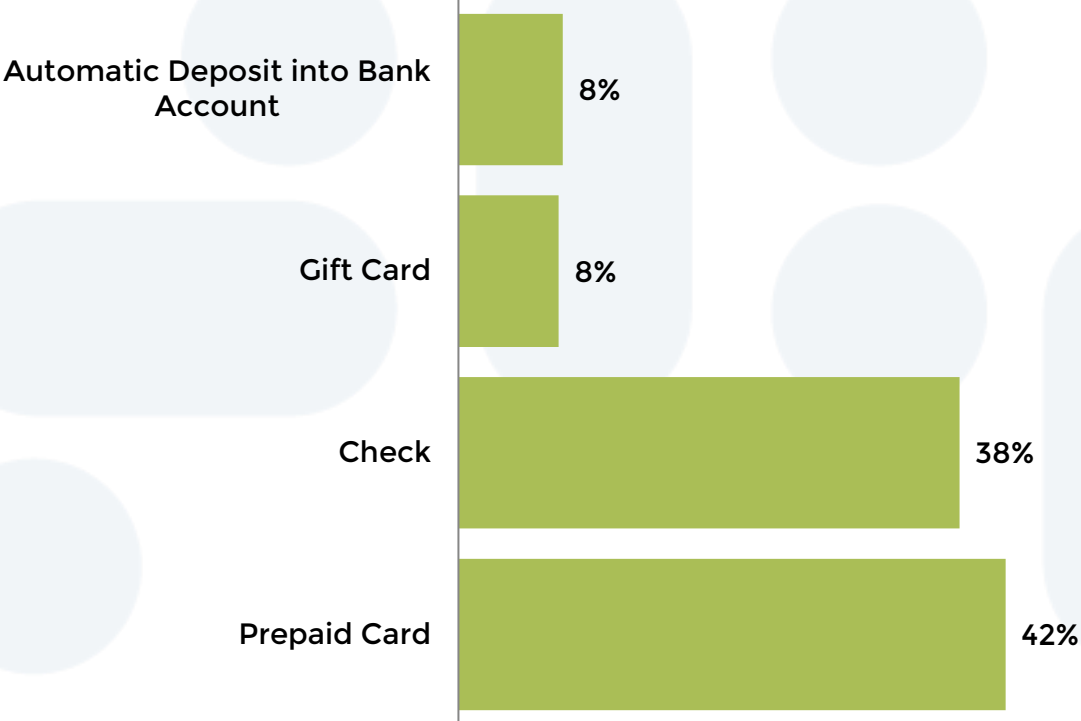


of patients said it took 2-12+ weeks to receive a reimbursement or payment

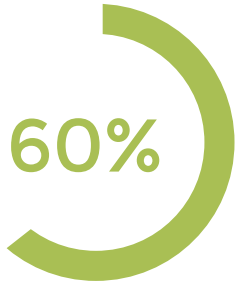


were paid via online portal

How did you receive your payment?



Patient Experience - Payments



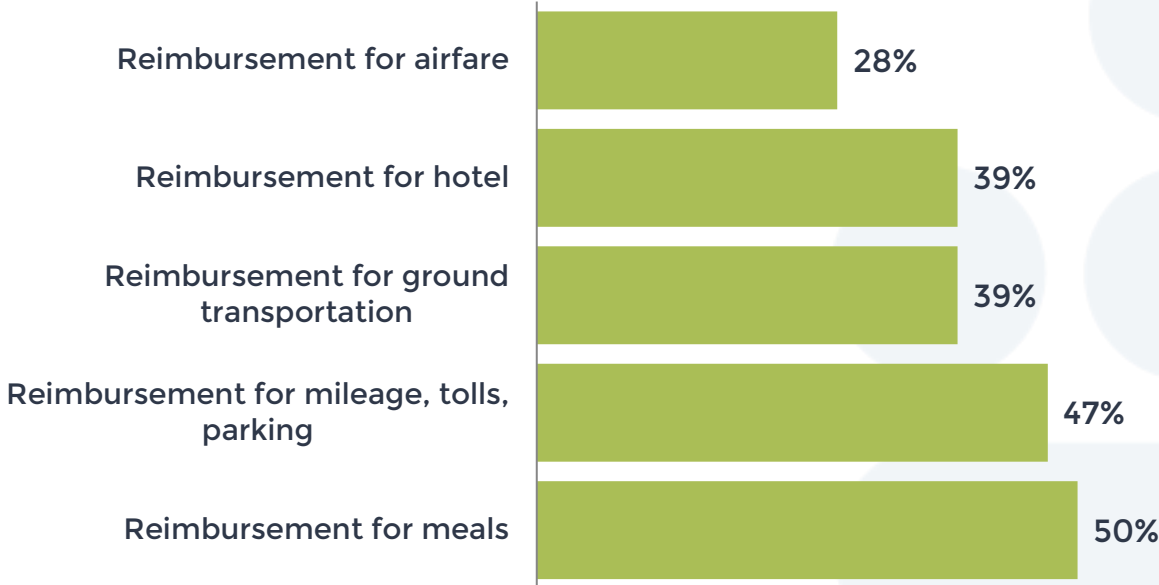
of patients received some type of payment for participating in the clinical trial

Payments ranged from a minimum of \$25 to a maximum of \$900 with a mean of \$208.65

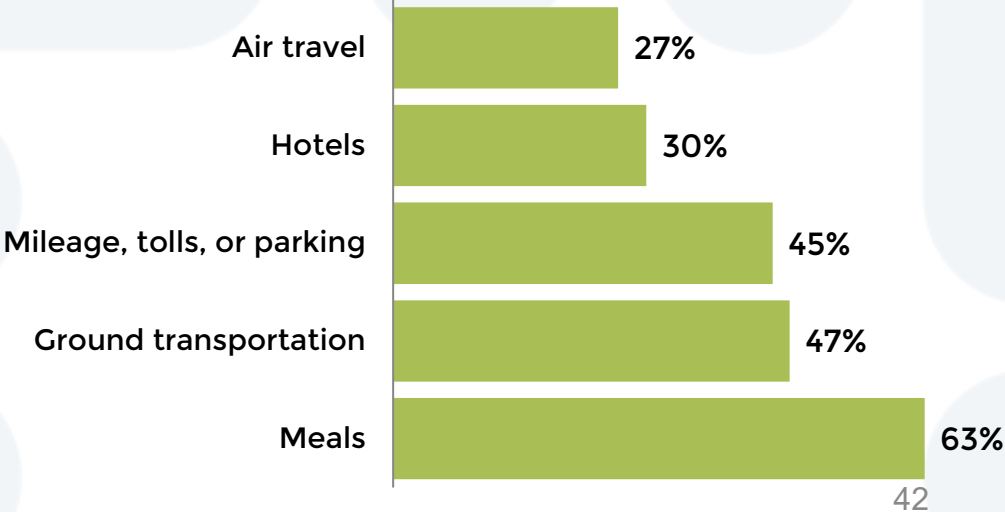


received a flat fee or stipend for each visit

28%-50% were reimbursements for various expenditures, including:

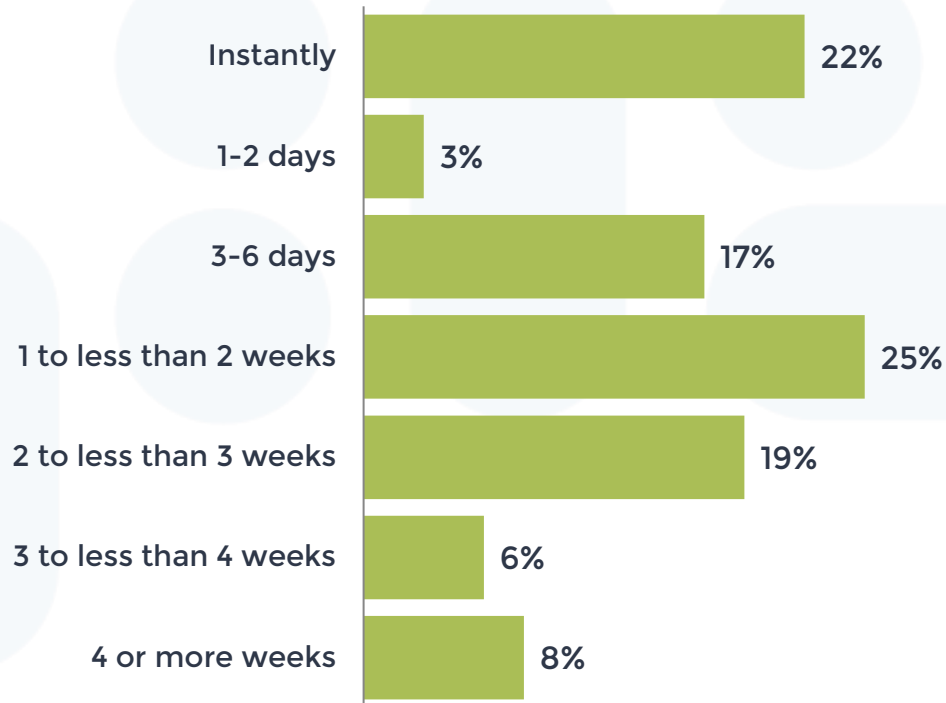


While some patients did not receive any reimbursement for out-of-pocket travel expenditures related to their trials:

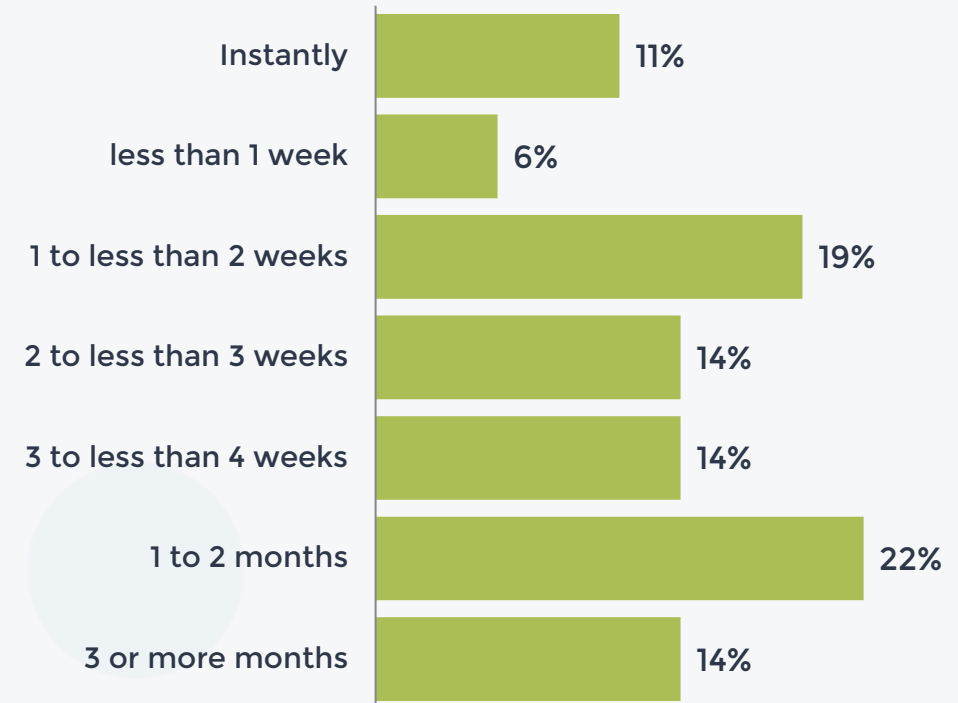


Patient Experience - Payments

42% of patients received payments in less than one week:



While 83% of patients received payments taking 2 weeks - 12 weeks+:



Impact of Financial Issues on Participation



of caregivers said financial burdens were a big reason to not participate in a trial



of caregivers said they received reimbursements for trial-related expenses



of caregivers said receiving reimbursements for trial-related expenses made it easier to participate

Caregiver Experience - Payments

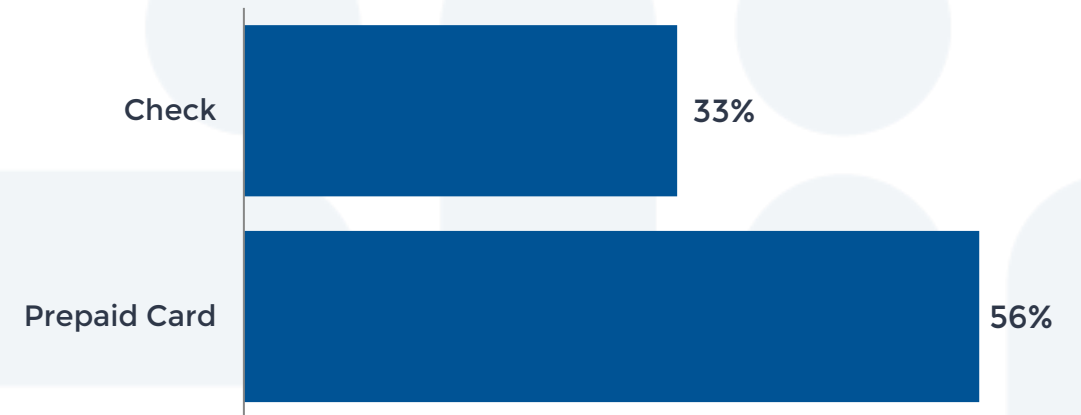


of caregivers said it took 2-12+ weeks to receive a reimbursement or payment



were paid via online portal

How did you receive your payment?



Caregiver Experience - Payments

42%

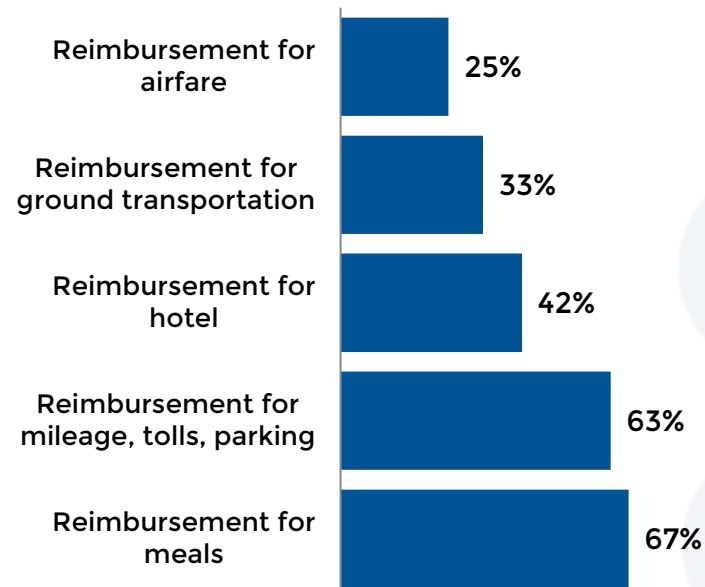
of caregivers received some type of payment for participating in the clinical trial

Payments ranged from \$25 - \$2000, with a mean of \$298.89

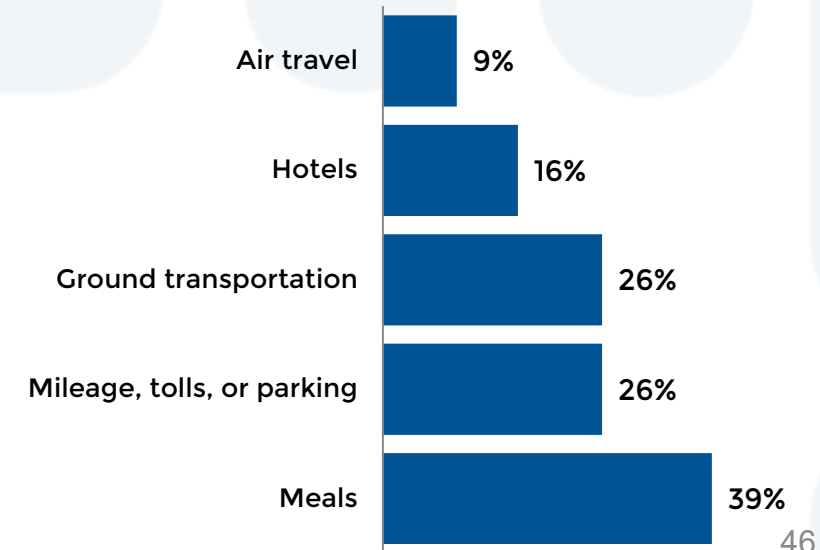
75%

received a flat fee or stipend for each visit

25%-67% were reimbursements for various expenditures, including:

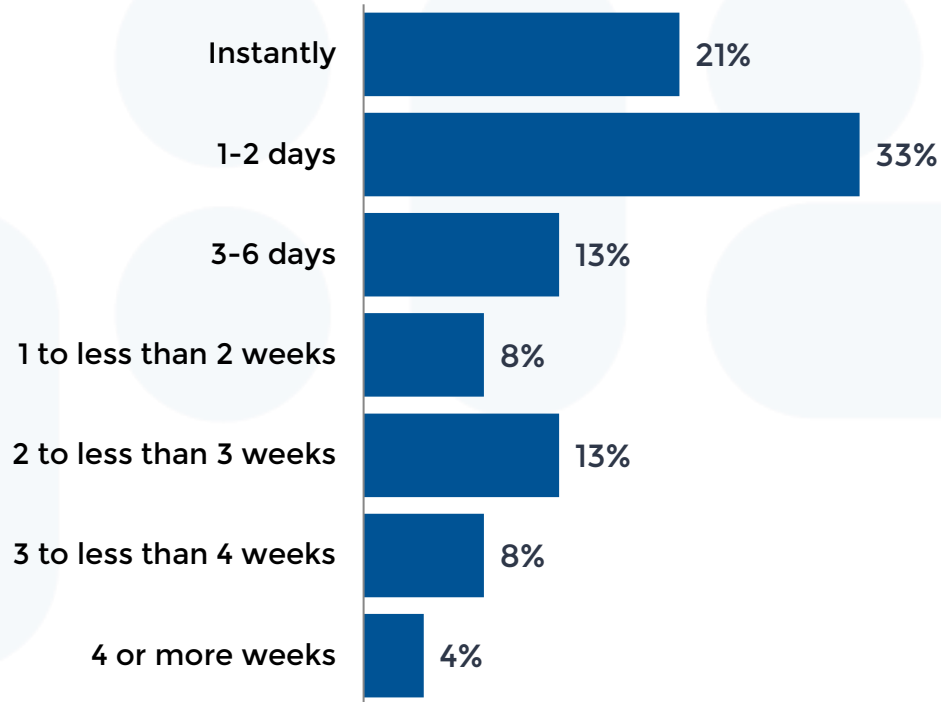


While some caregivers did not receive any reimbursement for out-of-pocket travel expenditures related to their trials:

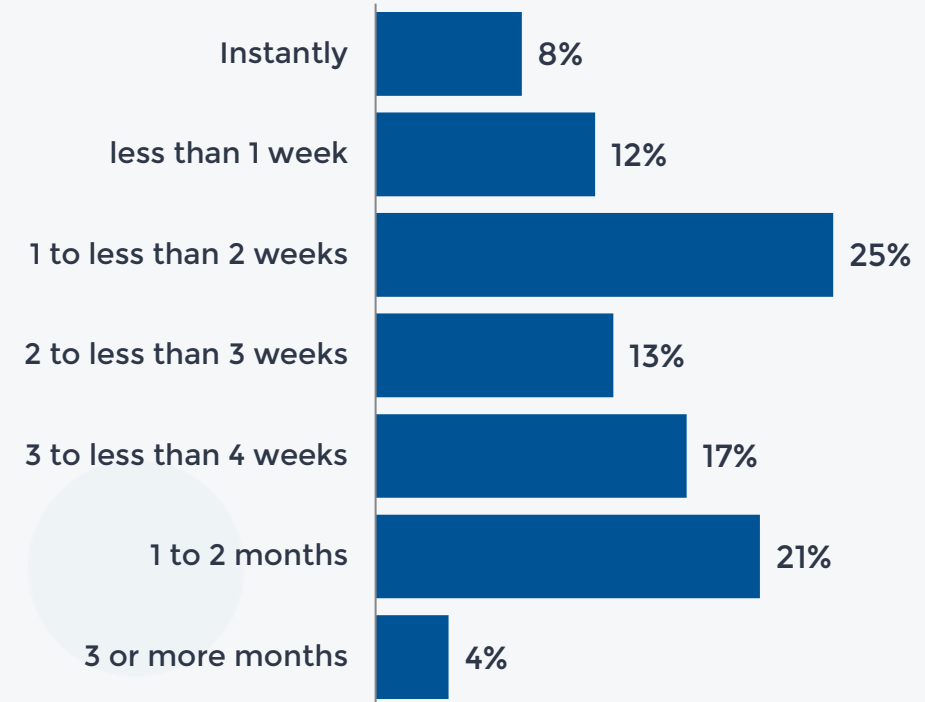


Caregiver Experience - Payments

67% of caregivers received payments in less than one week:



While 80% of caregivers received payments taking 2 weeks - 12 weeks+:



What are your unique financial burdens?

HOTEL:

“The hotel expenses because of the plane cancellation. The trial my son is on we pay for travel. If there was a way to get more support, I would travel more frequently for the treatment every 6 months instead of once a year. I fundraise, sell, scrimp and save to pay for expenses gladly because it helps my child. We travel with nurses and family, so we need hotel rooms for two weeks as well as meals and other expenses. It’s costly. But I would sell my car if it made things better for my child. There are always unexpected costs in traveling with someone disabled.”

CREDIT CARD:

“The financial issues I had were when the hotel required me to give a credit card for incidentals. I didn’t have a credit card so had to give them my debit card. They held a few hundred dollars on my card until checkout. It was difficult for me at the time because we had to buy meals and didn’t get reimbursed until a few weeks afterwards.”

LIMITED INCOME:

“I am on SSI and it’s my only form of income and I have to make it last all month. I primarily participate in trials to help others learn more and to fight for cures, but compensation for at least gas/travel arrangements would be super helpful.”

INCOME LOSS:

“I was broke from becoming ill and had no income or benefits coming in so affording a hotel was very difficult and searching for a cheap flight.”

OUT OF POCKET COSTS:

“The trial I had to turn down (that I really wanted to participate in because it would've been useful research but also beneficial for my own medical reality) was turned down because 1) the trial didn't cover airfare and was in another state, and 2) they would not provide lodging in a manner that was safe for me with COVID (I'm very high risk). Having to pay for airfare out of my own pocket, and then potentially my own safe-for-me lodging as well was just too much in addition to the lost wages at work during that period.”



SECTION 6

Trusted Relationships and the Importance of Communication

Importance of a single point-of-contact



95%

of patients said having a single point-of-contact to assist/support them in the clinical trial was important



98%

of caregivers said having a dedicated person to help them manage trial logistics was important



Who helped the most?

- Having a key contact was critical
- This person made a personal connection to people in the trial
- 24/7 access was also important
- Study coordinators play a key role

“The **Patient Lodging Coordinator** helped me finally get safe, comfortable lodging...and it only cost a bit more than I was paying to stay at run-down motels. The **research nurse** has also been extremely helpful; she made sure I understood everything: all the procedures I'd be undergoing in order to qualify, the side effects other patients had already reported, and anything else I had questions about.”

“The **study coordinators** at both study sites that we screened for were the most helpful. They were the go to for all of our concerns, contact information and put us in line with the travel agents who booked everything. The coordinators walked us through the paperwork and all of our responsibilities. I was able to reach them at any given hour and they understood our unique family needs and made sure all was arranged to make a smooth travel.”

Who helped the most?

- Family members
- A few had companies that helped with logistics and trial participation
- A key issue is dealing with changing plans and unexpected problems
- A few said no one helped them all that much

“It is difficult to say who helped the most. There were 3 key people:

1. The **company that provided the infusion** my husband takes, worked with our insurance and the test site to set up the infusions.
2. The **head researcher's assistant** helped set up the allergy shots.
3. **My husband's sister** was at the test site for 3 months before us because her [child] was participating in the same study. She let us know everything that was provided. Gave us ideas of what she brought and what was lacking. As the caretaker, she was the one who helped me the most.”

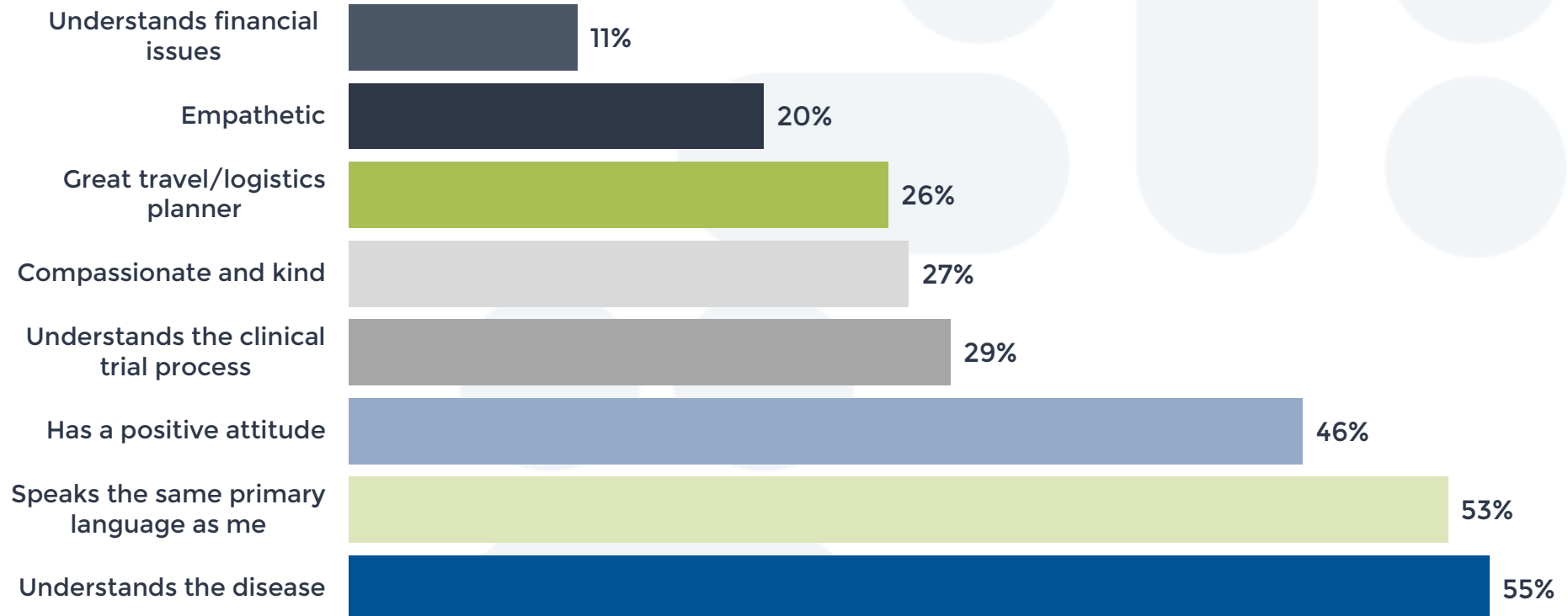
“The **lead clinical study nurse** was phenomenal. Whatever cropped up she was always there to help us or at least direct us to someone who could. If she couldn't deal with it herself rather than just take the easy way out and say no...she would say well let me see what I can do...and she always came through for us. I can't imagine participating in that study without her help. But it was more than just administrative efficiency...**[nurse] saw us beyond our role as a data point and connected with us as humans and worked hard to pay attention to the "human side" of the equation.**“

Patient Experience - Support

100%

of patients said having a support person who **LIVES IN THEIR TIME ZONE** was the most important element to patient support.

Additional characteristics are ranked below:



Patient Experience - Insights



Do I have everything I need?

“Ugh... how will I carry everything all by myself to and from the car and hold an umbrella in the storm too?”



Will I be driving in bad weather?

“Will I have to make a detour if the road is closed due to bad weather or construction? Will I get lost? How do I get back safely?”



Praying that I get there safely and back

“Please give me the strength and courage to make it through this day and get to the clinical trial safely and back home again.”

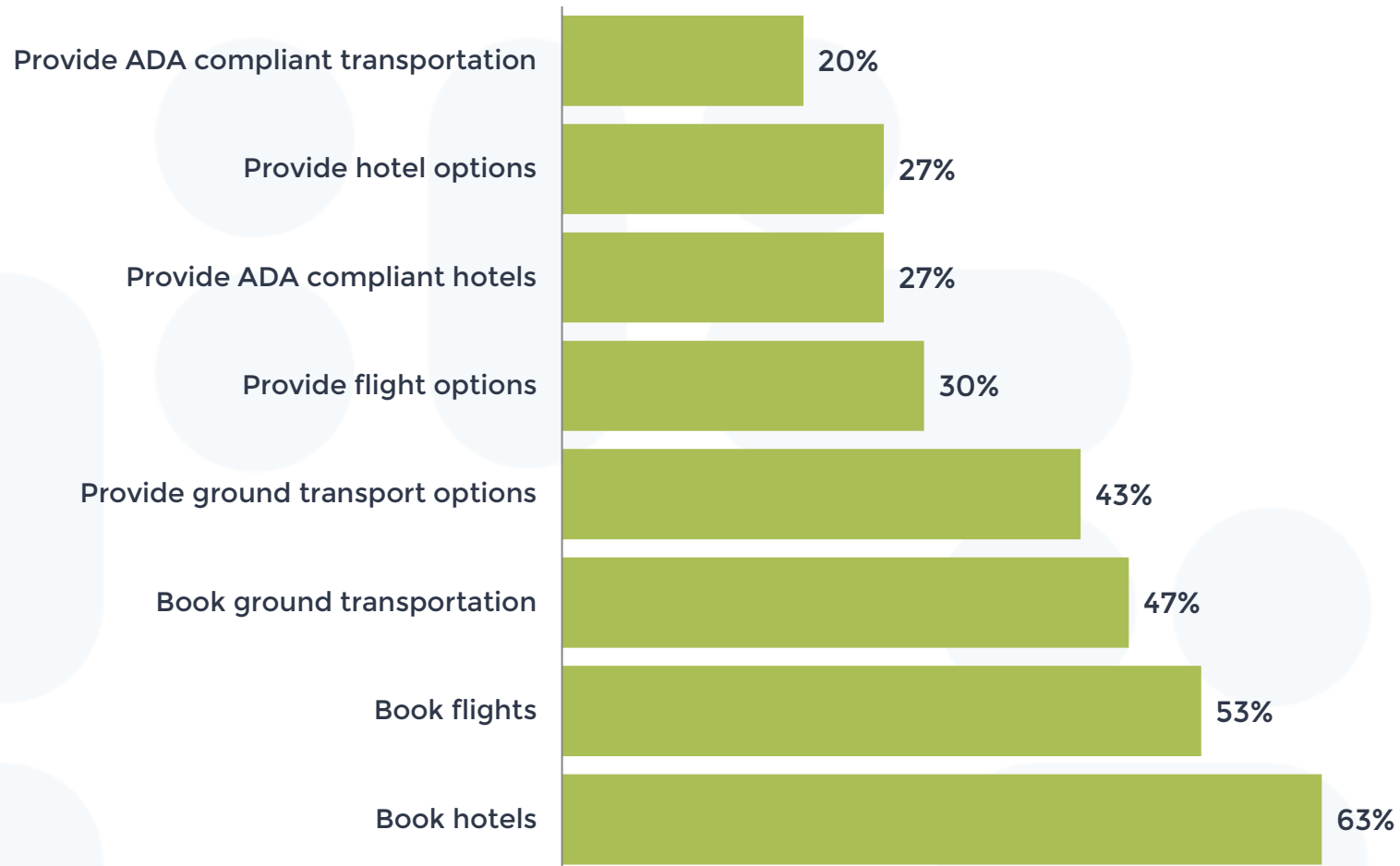


How much time will it take?

“Will I be late for the trial? Should I drive another way? Should I leave 4 or 5 hours before I need to be there? How long will the trial take this time, and will the investigator and medical students not show up on time and I will have to wait another 1-2 hours before we begin? Will it be cancelled when I get there after I spent all that time driving?”

Patient Experience - Support

Patient support services included:

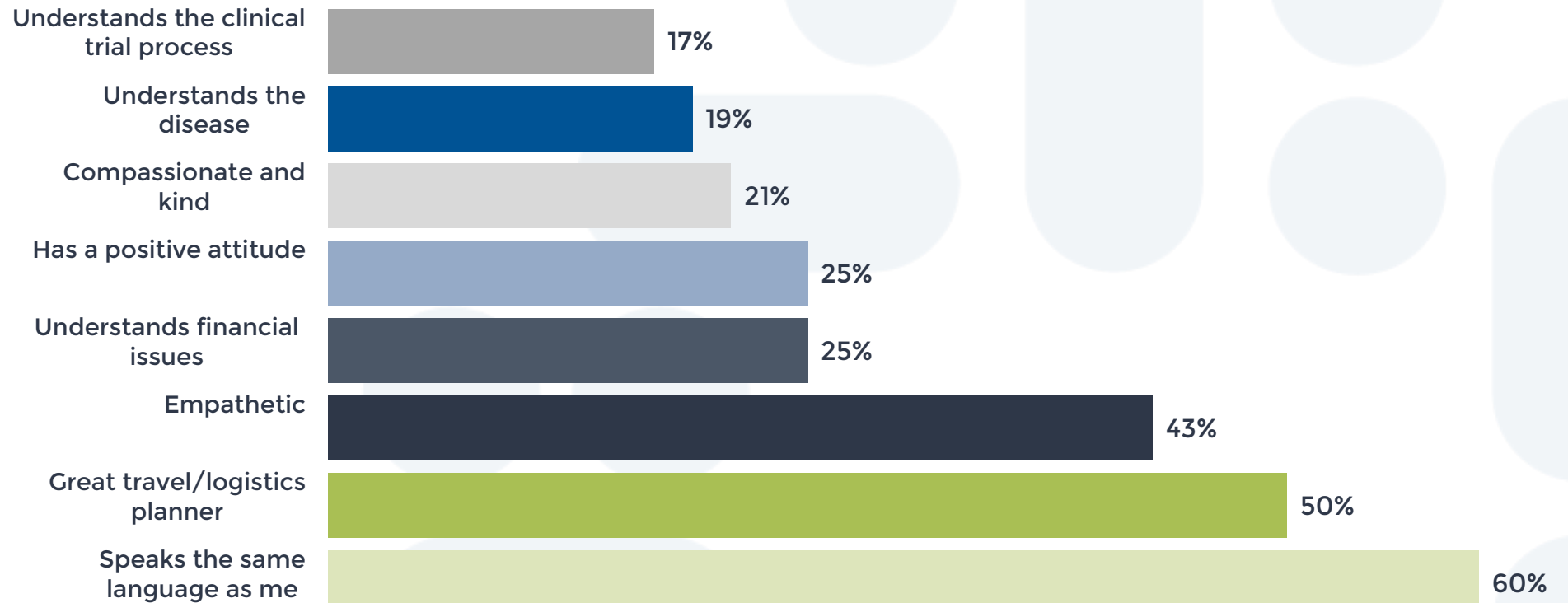


Caregiver Experience - Support

100%

of caregivers said having a support person who **LIVES IN THEIR TIME ZONE** was the most important element to patient support.

Additional characteristics are ranked below:



Caregiver Experience - Insights



Life of a special needs mom

"I'm sure every mom (or dad) feels like they have the weight of the world on their shoulders, but the shoulders of a special needs parent are even more weighed down. Are you making the right decision? Will we be able to add more to our already full plate? Will my child be able to handle the travel, meds, lab draws etc.?"



All the balls in the air

"All of the balls in the air and I'm juggling them or at least attempting too. Each one represents a single thing I'm responsible for. Drop one and they all fall."



risk >/< reward?

"Do the potential rewards of the study outweigh the potential risks? What if something happens and she's never the same? But also, what if her life, all of our lives are improved?"

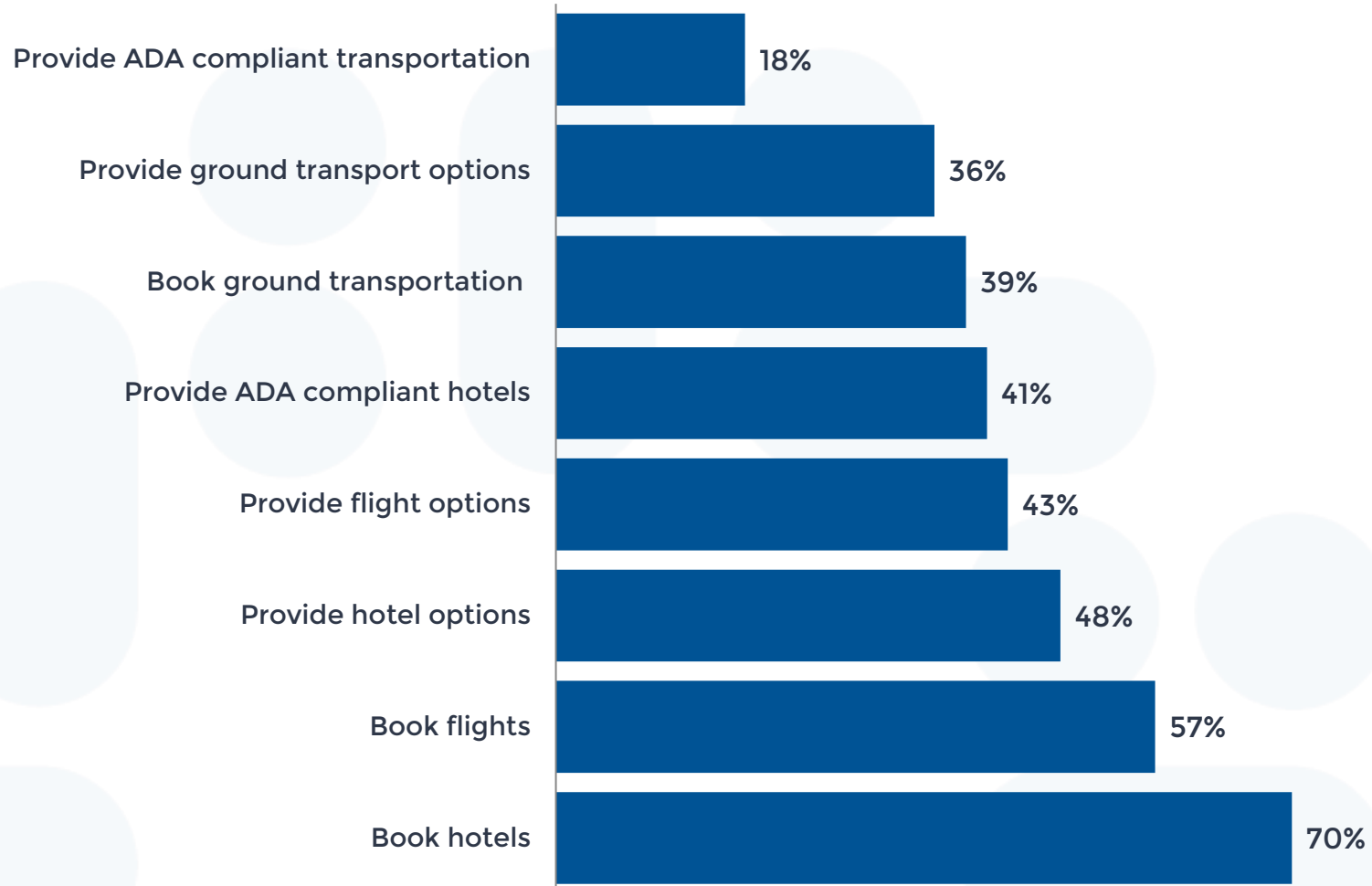


Guilt of doing this TO my child

"No one is telling me to do this. The decision isn't life or death but could potentially improve it. I am making a deliberate decision to do this to my child. What if I choose wrong?"

Caregiver Experience - Support

Support services included:



Unique travel issues:

UNCERTAINTY:

“When flying, the airlines were occasionally unwilling to put out the ramp for my child to get into the plane. They didn't know we needed that until we checked in and I asked at the gate. I think that could have been avoided if a coordinator helped with reservations. Also, I was trying to figure out which worked best: being first on the plane or last. If we were first, everyone was waiting behind us, if we were last, it was difficult to get through the aisles. Again, a coordinator could have helped. It was the uncertainty every time we flew.”

SUPPORT ON THE FLY:

“The only issue I ever experienced was, once the hotel tried to charge me for the entire stay, but it was a mix-up and my travel coordinator quickly took care of it. We did experience some delayed flights, and the coordinator made sure to reschedule ground transportation when that happened.”

ACCOMMODATIONS:

“I had to find a homeless shelter to stay in after the study. It wasn't in any condition to cater to someone who just had a stem cell transplant. I had to get my family from out of state to come get me as I was in no condition to drive or fly.”

COORDINATION:

“I think not having a coordinator is the most difficult thing one can experience, along with not being able to afford the travel and expenses.”

PROACTIVE PLANNING:

“Letting the airline know my autistic child would be traveling ahead of time and making accommodations for his situation would have been wonderful for flights and delays.”

PROGRESSIVE PLANNING:

“I will now need to fly in an air ambulance, with additional luggage for medical needs/equipment and require a wheelchair accessible van. Since we've continued to use the same point person, the planning stage is super easy and painless, and she knows how to care for us! She is always willing to help & available for whatever needs might arise.”

Patient – “Ideal” Support Company

- The ideal company understands, cares, and sees you
 - Some hire people who have had the disease
 - Others hire social workers who understand
- They are empathetic and show it
- People who are available 24/7 to help with the unpredictable issues as they arise
- They know everything about planning and setting up checklists and itineraries
 - One patient said her ideal company hired event planners
- They help manage stress and anxiety
- They help with finances with prepaid debit cards
- They help with the home and family

“We'll call our company the **We Know What You're Going Through** Company.”

“The company likes to employ people who understand and possibly have gone through a clinical trial either themselves or with a loved one.”

“VISION OF **HOPE** hire staff with same vision of giving patients the caring environment, They don't need worry about overall care from start to finish of treatment.”

“Our staff of coordinators is **available 24/7** to answer questions about logistics, appointments, travel, back up plans.”

“If you need a specific type of lodging, we will try to find it; if you do not drive and cannot find someone to drive you, we will work out transportation; we will talk about your needs at home (childcare, elderly parents, pets, etc.); **we will focus on you and keeping your trial running smoothly.**”

“H.E.R.O. Clinical Trial Assistance (CTA) and its team of social workers, travel agents, and motivated young interns, **all of whom have a connection with cancer,** are here to make getting to your clinical trial site as smooth as possible... You are a hero for participating in a trial, so H.E.R.O. is here for you.”



Patient Letter

Company Name:

Less Stress Clinical Trials

Clinical C.A.R.E.S.: Creating Accessible & Reliable Experiences Safely

We would hire people with medical diagnoses who can relate more to the issues surrounding travel and clinical trial participation. This would include those who have been previously diagnosed with cancer, wheelchair users with or without rare diseases, people with autoimmune disorders, etc. It would be a work from home position to ensure the safety of the employees.

We would provide patients and their caregivers with a prepaid debit card to be used for travel expenses, within the limitations of the study (a set amount for the entire trip). This card would be mailed to them prior to travel. We would arrange for all transportation needs, including ground transportation and/or air transportation between home, hotel, and clinical sites, as needed. The hotel would be arranged by us, with input on special needs requirements from the client (patient). If they have any pets or children that need care while they are away, we would help find them reliable options and assist in any financial burdens this may cause.

As with anything, stress and anxiety can occur and we will be available to support them, as needed. We will employ some people with therapeutic backgrounds and/or provide training to our employees to help ensure as less stress as we can for our clients (patients). This can be an amazing experience if the right people are involved, and the clients (patients) are provided the right supports.

Caregiver – “Ideal” Support Company

- Caregivers ask for more of a “family focus” than the patients
- The family, not the caregiver or patient, is the unit of focus
- Yet they want the same big picture themes:
 - A company that understands, cares, and sees us
 - Excellent planners who anticipate issues
 - People who make lists and itineraries
 - People who reduce our stress and anxieties
 - They help with the finances and travel details
- People who help with the family and home life while we are away
 - Kids to and from school, feed the dogs
 - Water flowers, take out trash, pick up packages

“This company hires caring **travel agents, social workers, insurance lawyers and counselors** to help people navigate the trials of those participating in clinical trials.”

“Your concierge will **communicate** with you ahead of the clinical trial to create the perfect logistical plan catered to your individual needs. Need help getting to and from your clinical site? you tell us what you need! prefer to fly? got it! Need a car service? **we've got you covered!**”

“Our staff is trained to understand the many different problems and situations patients and their caregivers may encounter during a clinical trial. We are **experts in listening and problem solving** and trouble shooting.”

“There would be **one person assigned to each family**, so they could get used to dealing with the same person. They would understand the individual needs and issues of that family.”

“Company Name - trusted care. Their priority focus would be on **making the family feel comfortable** using them, taking the time to get to know them, and handling every last detail of clinical trial logistics.”

Caregiver Letter

Company Name: Caregiver Concierge Services

Welcome to the company that will be your right-hand man/woman! as you navigate your upcoming clinical trial. You name it, we will help!

We only hire **compassionate, driven, problem-solvers.** Set your mind at ease knowing they have all been vetted and fingerprinted in the FBI national database.

Your family will be assigned your very own concierge who will help navigate the entire process with you and hopefully anticipate any needs you might have moving forward.

Your concierge will communicate with you ahead of the clinical trial to create the perfect logistical plan catered to your individual needs. Need help getting to and from your clinical site? you tell us what you need! prefer to fly? got it! Need a car service? We've got you covered! Would you rather travel in your own car? We can help with that too! **Need caregiver assistance for your other children or elderly parent? Done!**

Our services will also **help you get things squared away at home** so you can travel knowing everything has been taken care of. We will help with paying of any additional caregivers you might need to watch your other children at home.

With your **prepaid debit card** (a flat \$50 preloaded to get you started on your trip) and app you can travel knowing you won't have to worry about where the money to get to your clinical site will come from. Easy to use and with the app you can upload receipts directly in to get real time reimbursements for anything above the preloaded amount. Within the app you will also find all of your travel details. Hotel reservations, car service details, etc.

If while traveling you encounter an unexpected need, simply contact your concierge to handle that for you. Think of them as your personal assistant!





Letters to a Future Patient or Caregiver

Key themes in letters

- Preparation is key, so plan and have backup plans
- Make lists, especially for traveling
- Keep the contact numbers with your travel itinerary
- Your disease is unique, so don't allow yourself and your kid to be put in a cookie cutter mold
- Plan for two days of mental decompression when you get back
- Financially tough and mentally exhausting

“I knew from the beginning that without clinical trials, we really had no hope... In my eyes, he is busy being **a real life super hero.... a REAL world changer.**”

“Always plan for at least two days or mental decompressions after your trial visit, **don't expect yourself to get back to normal right away.**”

“Your **hope is stronger than your fear.**”

“**Make sure you have the name and number to the contact person** who will be planning and troubleshooting any problems you may encounter.”

Key themes in letters

- Educate yourself about the disease
- Ask for help as many will gladly assist
- Help child have pride, interests, and advocate for him/herself
- Allow child to have a say in their treatment
- If having a procedure, have doctor/nurse perform procedure first on a stuffed animal

“One biggest lesson I learned myself was **never give up..., no matter how hard times get keep your faith.** The unknown is the biggest fear but it also holds the possibilities of best results.”

“**Don't be afraid to ask for help** along the way. Whether its at the airport, hotel or the site, someone is always willing to lend an extra hand.”

“If I can say one thing about a clinical trial visit, is to **enjoy the time.** Treat it as a short getaway that allows you a change of scenery for a couple of days. **Treat it as a way to relax** in a nice hotel, enjoy a city that you may not visit otherwise and the people you meet along the way, are usually kind.”

Offering Advice and Wisdom

Dear Andrea,

I've been on this journey to find that magic wand we cancer patients long for and sometimes we travel a little further in hopes the "cure" is attainable. Remember nothing is set in stone and flexibility is the key.

Travel can be a breeze, or we can encounter hiccups along the way. Ideally getting on a magic carpet and taking a ride would be awesome but we don't live in that world so planning ahead is so helpful. I love the peace and quiet of my car but it's not peaceful in traffic or in bad weather. So maybe a train is a better option. Airports can be overwhelming but if the distance is great then time is valuable, and a plane might be a good option. Make sure you discuss possible hotel options and if it's paid for by the trial. How you decide should be discussed with your clinical trial team, your family/friends, and mostly your comfort level.

Do you love food? I do but I haven't eaten meat in many years, **so I shared with my trial team that anything offered needed to be vegetarian. Make sure you have snacks.** It's good to have a stash to munch on for the trip or during treatment. And plenty of water – a refillable bottle is so helpful.

Money...the 5 letter word that we all do not want to talk about but haunt us as cancer patients. **I was uncomfortable talking about money before I was diagnosed so the conversation did not get an easier but it's necessary.** Ask about compensation for the trial and what the compensation covers. Does your insurance get billed and are you responsible for the co-pays and deductible... Travel, food and lodging all add up plus if you need childcare. Being a patient is expensive so ask about organizations or grants that might help if the trial does not cover out-of-pocket expenses.

A support system and asking for help in my mind go hand in hand. I rarely ask for help for fear that I will be a bother but I'm the first to help others. **Don't be me. Don't ask for general help; be specific in what you/family need. It doesn't matter if you think it's trivial; people want to feel "useful" to you. ASK!** You can have someone set up a meal train for your family or play dates for your kids.

Be proactive in your clinical trial. **Ask questions. I've always said cancer is a roller coaster...the ups, downs, twists & turns...but the actual ride ends while treatment continues. It affects us emotionally, physically & spiritually and asking for guidance is not a sign of weakness but strength.** Whether it's a peer, I love my cancer family, or a professional we all need someone to lean on that gets "it" and doesn't judge. And there will be days that it's hard to put one foot in front of the other and get up and start the trial journey and there were 1 or 2 times that I picked up a phone and said I cannot today...I needed a break. We cannot lose ourselves and I hope your journey is successful medically and you still have your voice but stronger.

Offering Inspiration and Encouragement

Hello,

Chances are you reading this letter because you have a loved one that you are considering a clinical trial due to a diagnosis that has already affected your life so much. I would like to speak to you on behalf of my personal experience as a caregiver (mother) of a child who received the terrifying news that my son has a terminal disease and in time, without treatments, will eventually lose the ability to hug me or even lose the ability to feed himself without the help from others. His body will fail him completely and there is absolutely nothing I can do. I can't save his life with money or love and sadly, I can't take it from him.... Even though I would in a heartbeat if that meant saving his precious innocent life.

I knew from the beginning **that without clinical trials, we really had no hope.** Not only for my own child but for the future generations as well. My son began the journey with his clinical trial with weekly infusions at a young age. We traveled out of town weekly for several years for infusions and assessments. He wasn't gearing up to play the next sporting event at school or running around with friends. In my eyes, he is busy being a real-life superhero..... a REAL world changer.

Not knowing the data or side effects is SO very hard. You will have folders full of documents you have signed, and you will read the heartless comments about your child being a "lab rat" on online forums. You will run into people who may disagree with your decision. I like to think that if they were in the same situation with their own loved one that they too would **fight** and **HOPE** for a miracle for their loved one, like I do for my own child. It's not an easy journey watching your child go through the unknown. Hearing other kids screaming in the next room as they get their next blood draw or IV administered. My own son is able to now help these kids navigate through things that were once hard for us both.

Financially, it can be tough. Mentally it can be exhausting. Allow yourself time. I can't tell you how many times I have cried on a flight back home from across the country just praying to God that the data from this treatment will lead to something useful. I also cry because clinical trials can end at any time with no warning whatsoever.

Don't be afraid to ask for help from others. I am the first to admit that I am the worst when it comes to accepting or even asking for help. I want to do it all and that is a huge downfall for me, mentally and physically.

I have had the opportunity to meet some wonderful people throughout this journey. I have cried with strangers on an airplane as my exhausted son sleeps on my lap. I have cried and punched my steering wheel many times at 4am while driving to the busy airport because the thought of another infusion breaks me...

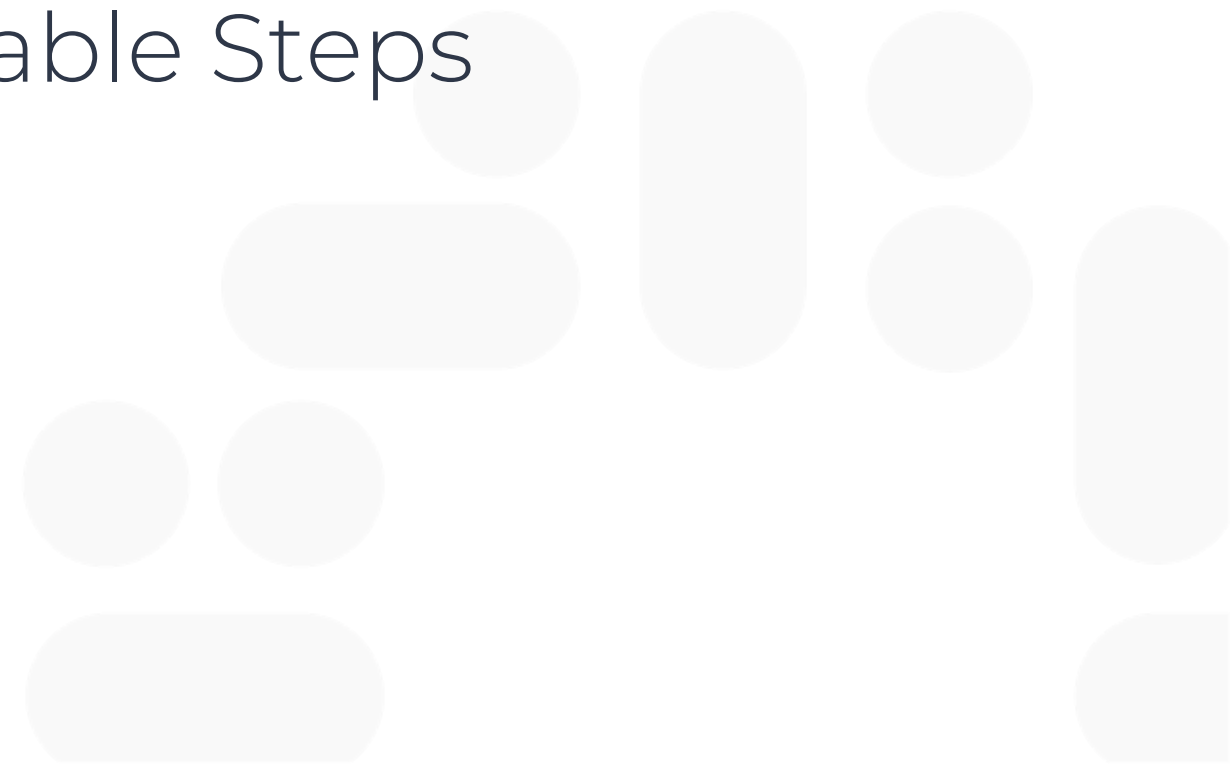
Allow yourself time to cry in the bathroom. Buy a punching bag for your garage. Ask questions. Be prepared the best you can. You are already being faced with such difficult decisions that many will never understand. Don't believe everything you read on the internet. Listen to doctors and the experts. Don't listen to "Nancy" on social media.

As a caregiver, you are already dealing with so much and I know it's tough. Clinical trials are not for everyone, and I get that, but without these trials for any disease, we lose hope and I strongly believe that. **Just know that everything** isn't always going to go as planned. That is life but you can control how you respond to things thrown into your path. **You are a world changer.**

SECTION 8



Executive Summary & Actionable Steps



1

The journey starts with finding a trial

- Patients and caregivers feel exhilarated, determined, and hopeful about a trial
- Yet they feel anxious and scared, because the treatment might not work
- Emotional, logistical, and financial burdens are factors to trial participation

2

Treatment and hope overwhelms all other issues

- When faced with suffering and death, people will do anything for treatment
- Their hopes and fears are centered on the benefits the clinical trial may bring
- Travel and logistics are important, but they are secondary issues

3

Uncertainty and anxiety

- Disease progression is uncertain, is the treatment working, are we on placebo?
- Clinical trial schedules change, and what are the side effects?
- Flights canceled, traffic jams, inadequate hotel facilities, uncertain costs and coverage

4

Feeling overwhelmed

- Clinical trial participation is extremely demanding, physically and emotionally
- Also demanding in terms of finances, paperwork for reimbursement
- The stress and challenges of managing the family are enormous

5

Planning and executing travel requires customization

- Travel requirements are unique to the disabilities and challenges of each disease
- They need planners and checklists to address all the contingencies
- Need help learning housing, travel, meals, traffic, etc., in the clinical trial city

6

Managing home, family, jobs while away, and then returning

- Planning begins with getting time off from work, arrangements for kids and household
- Then managing jobs, kids, household, pets, etc., while away
- Getting back from the trial is extremely difficult, and they need emotional help



7

Differences between patients and caregivers

- Travel and logistics issues are similar for patients and caregivers
- Caregivers often ignore their own needs, feel powerless, and sometimes guilty
- Caregivers with children have needs that are unique to the age and disabilities of child

8

Financial issues are a huge burden

- Many don't have the money, and paperwork with reimbursement is very difficult
- Few have adequate support for out-of-pocket expenses
- They prefer prepaid debit cards and fast payment

9

Patients and caregivers want key contact 24/7

- They need competency and access - some suggested event planners as staff
- They need anxiety reduction
- They need someone to help with the uncertainties - great communicators

10

They want help from people who truly understand and care

- Their ideal company is staffed with people who have had the disease
- People who are trained to deal with emotional and mental health issues
- The staff functions as family to solve the myriad of unexpected needs

11

Benefits to sponsors (of patient support services)

- Enroll more patients and therefore fill the clinical trial sooner
- Increase retention/reduce dropout rate, increasing the quality of data and speed to market
- Improve speed to market and reduce error in primary and secondary endpoints

12

Improved outcomes and achieving statistical significance

- We know relationships and stress affect outcomes of treatment
- Might relationship and stress reduction improve response to treatment?
- Many trials miss significance on primary and secondary endpoints by small margins

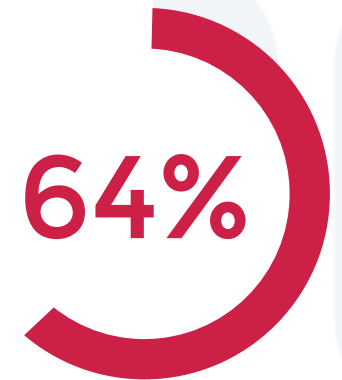


Actionable Steps

- Ongoing research to understand participation barriers and support needs
- Engage with patient communities and advocacy groups
- Identify participation barriers and proactively plan during early stages of trial design
- Educate and inform patients and trial sites of the availability and benefits of support services
- Leverage technology to provide customized support solutions



of respondents said having support services helped them enroll and stay in the trial



of respondents had a company which provided support services

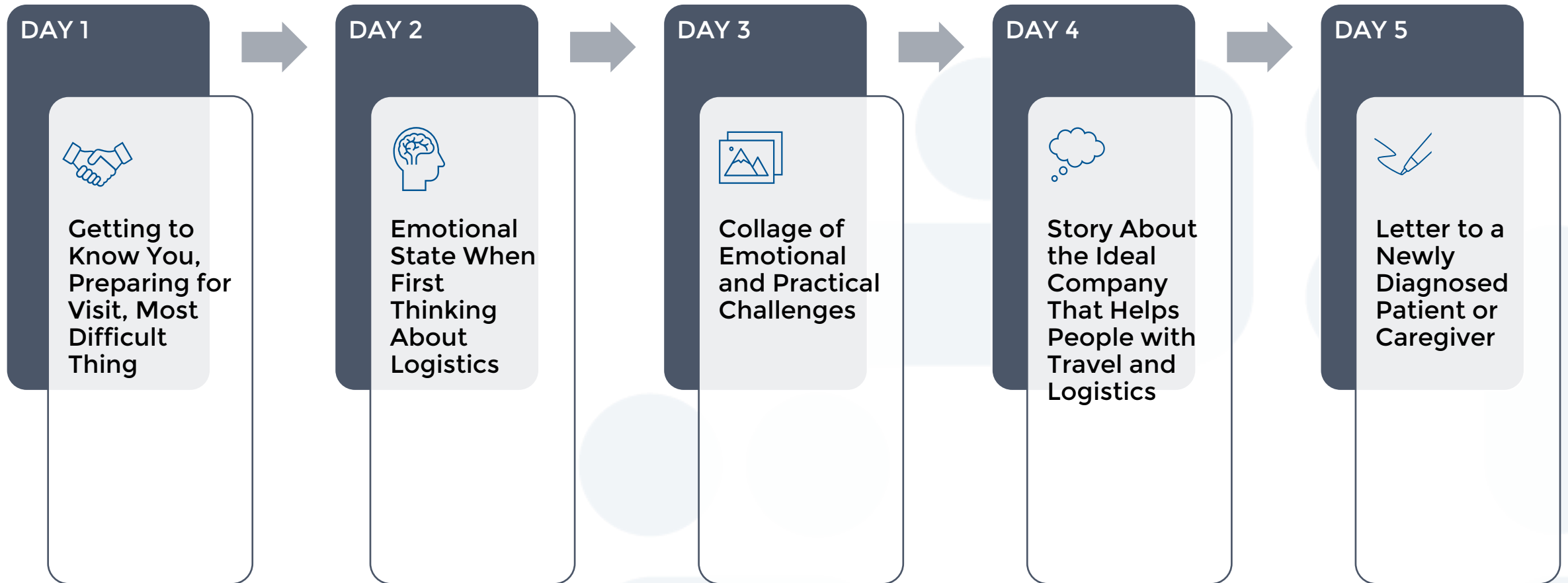
SECTION 9



Appendices


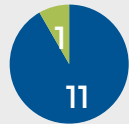
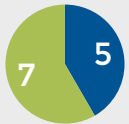
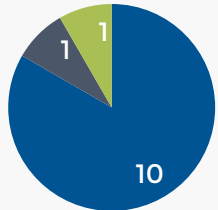
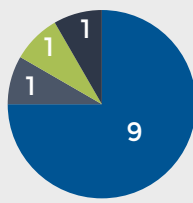


The Activity Guide




QUALITATIVE SAMPLE DEMOGRAPHICS:

Patients and Caregivers

	Patients	Caregivers	
		Caregivers	Recipients of Caregiving
Mean age (Age range)	45.9 (Age range: 25 to 61)	46.5 (Age range: 35 to 60)	<ul style="list-style-type: none"> 65.5 - spouse or parent 11 - child
Gender	 <p>■ Female ■ Male</p>	 <p>■ Female ■ Male</p>	 <p>■ Female ■ Male</p>
Still participating in study?	✓ 7 yes ✗ 5 no	✓ 9 yes ✗ 3 no	
Ethnicity	 <p> ■ White ■ African American ■ Asian </p>	 <p> ■ White ■ White & African American ■ Asian ■ White & African American & Hispanic/Latino </p>	

IRB Approval & Exemption Status Letter



6100 Merriweather Dr., Suite 600
Columbia, MD 21044
410-884-2900

EXEMPT DETERMINATION

DATE: 27 Apr 2022

TO: David Harris

PROJECT: Gray Consulting, Inc. dba Clinisigma, SURVEY OF THE EXPERIENCES OF PATIENTS AND CAREGIVERS WITH TRAVEL ASSOCIATED WITH CLINICAL TRIALS (Pro00062757)

DOCUMENTATION REVIEWED:

Protocol Version: • Protocol (Dated 5 April 2022)

Consent Form: • Informed Consent (Not Dated)

Other Material: • Near Final Survey (Not Dated)
• Final Survey (Not Dated)

Using the Department of Health and Human Services regulations found at 45 CFR 46.104(d)(2), the IRB determined that your research project is exempt from IRB oversight. The IRB also completed the necessary additional limited review considerations as set forth under the Revised Common Rule, 45 CFR 46.104(d). All study related documents will be removed from our active files and archived.


Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this exemption with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.
2. Should the nature of the research project, or any aspect of the study, change such that the nature of the study no longer meets the criteria found in 45 CFR 46.104(d)(2), you will resubmit revised materials for IRB review.
3. It is the responsibility of each investigator to ensure that the project meets the ethical standards of the institution. Specifically, the selection of subject is equitable, there are adequate provisions to maintain the confidentiality of any identifiable data collected, and when there are interactions with research subjects, they will be informed: that the activity involves research; of a description of the procedures; that participation is voluntary; and of the contact information for the researcher.

Page 1 of 2

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The IRB will evaluate the new information and make a determination at that time regarding the research project's status.

This project is not subject to requirements for continuing review.

If you wish to appeal the IRB's determinations and/or imposed modifications, please submit supporting documentation to address the IRB's concerns by creating an Appeal Modification in CIRBI.

If you have any questions or concerns, please use the Contact IRB activity on the Advarra CIRBI™ Platform.

Thank you for selecting Advarra IRB to review your research project.

Page 2 of 2

CONFIDENTIAL

APPENDIX D

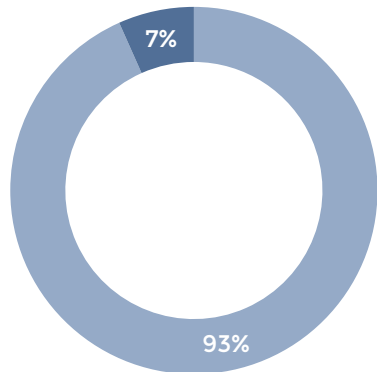


Part I: Quantitative Participant Demographics



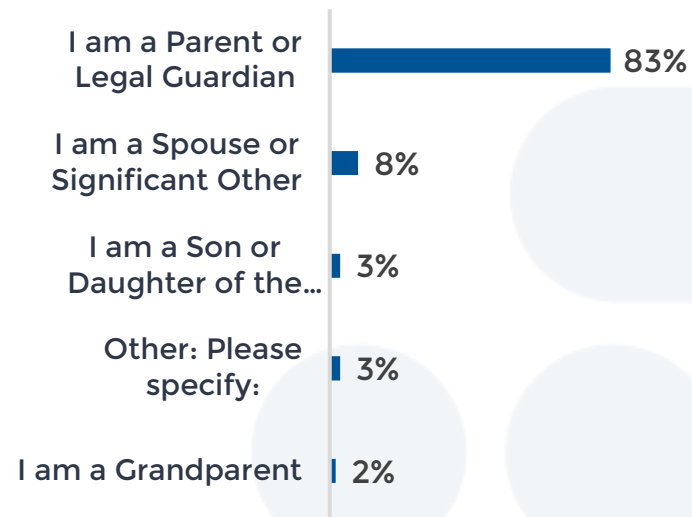
Sample Size (n=856)

During the time of the clinical trial, did the person you care for live with you, or in a separate household?

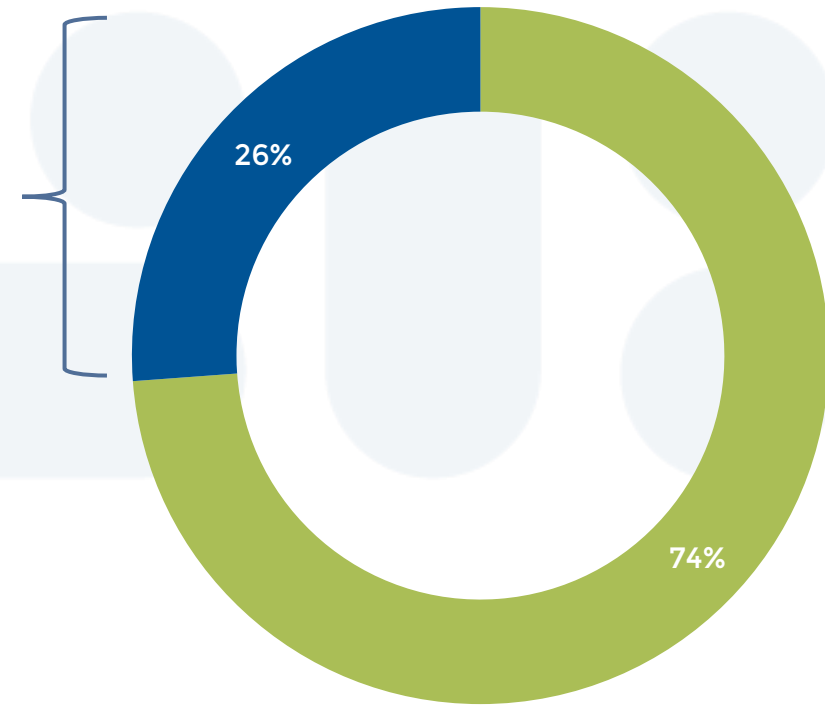


- Lived with me most of the time
- Lived in a separate household most of the time

What is your relationship to the patient or person you care for?



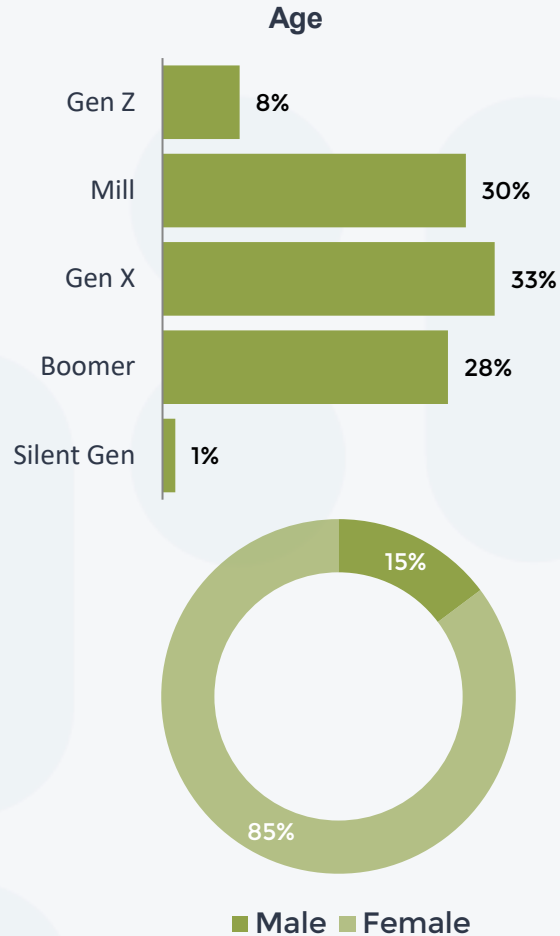
Are you a patient or a caregiver of a patient?



- Patient (n=632)
- Caregiver (n=224)

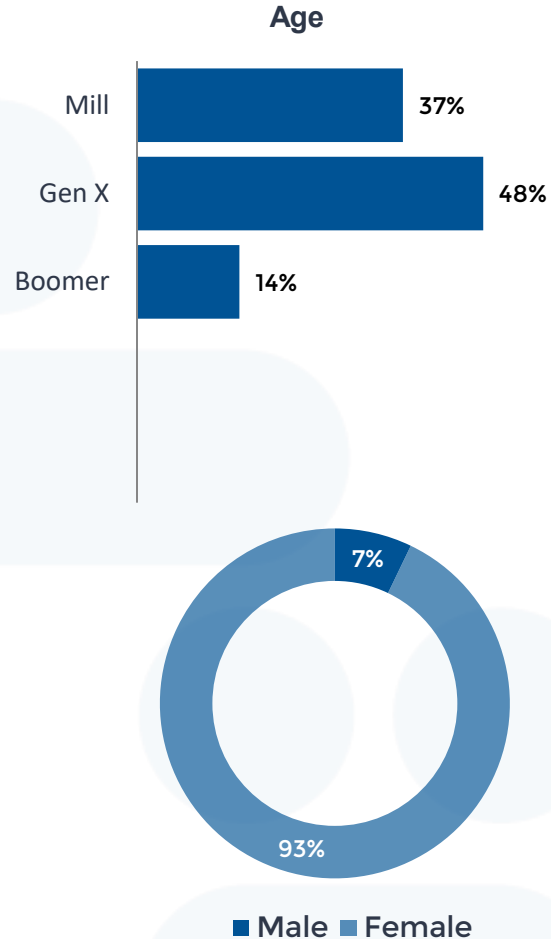
Age and Gender

Patients



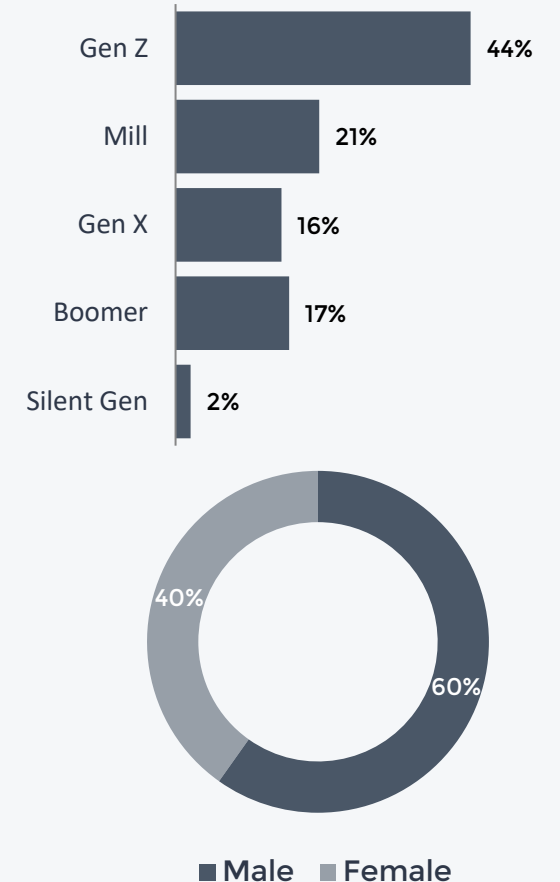
Patients: (n=632)

Caregiver



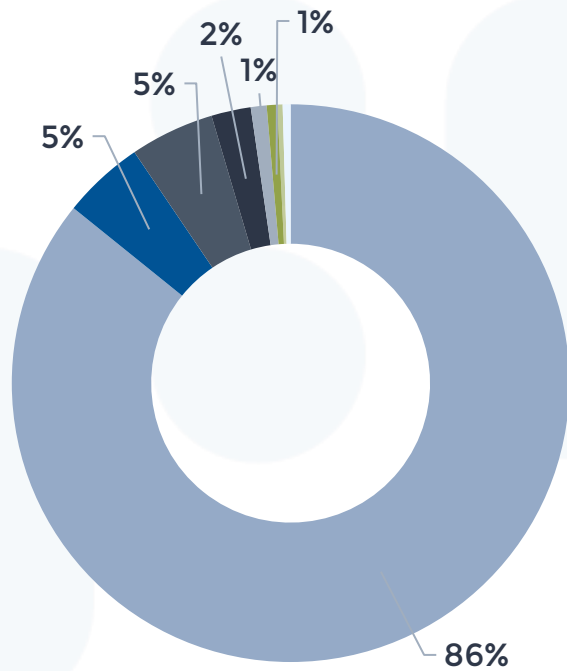
Caregivers: (n=224)

Person You Care For

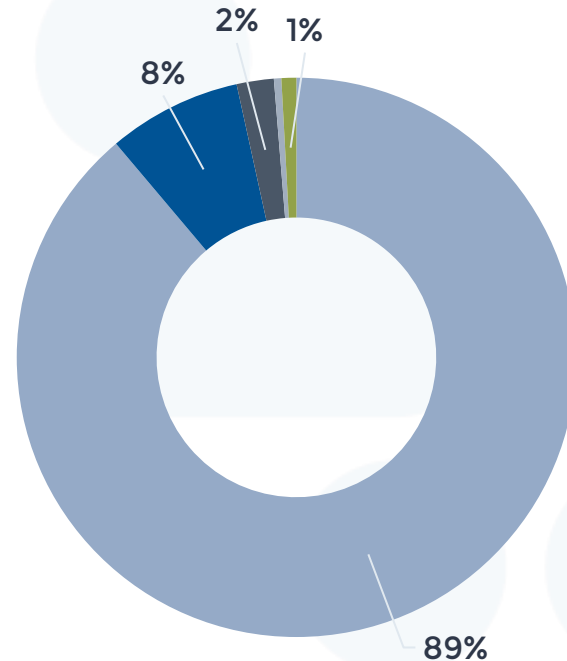


Ethnicity

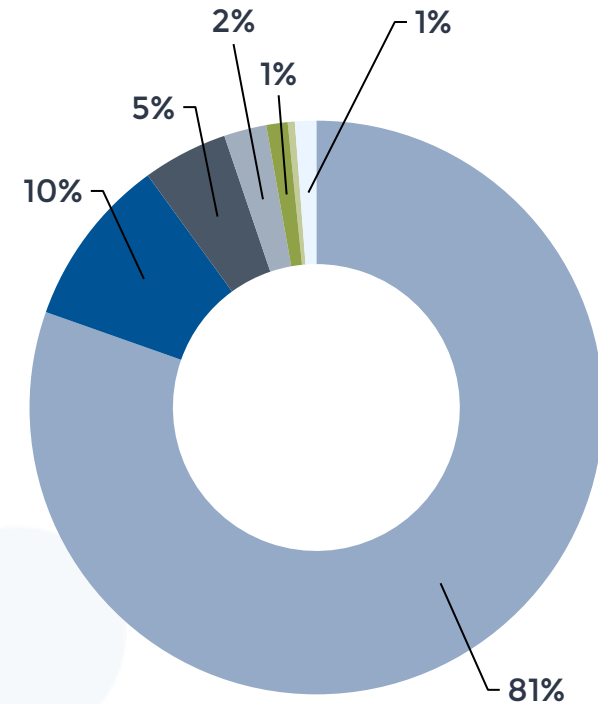
Patients



Caregiver



Person You Care For



KEY

- White
- Hispanic, Latino, or Spanish origin
- Black or African American
- Asian
- American Indian or Alaska Native
- Middle Eastern or North African
- Native Hawaiian or Other Pacific Islander
- Some other race, ethnicity, or origin (Please describe:)

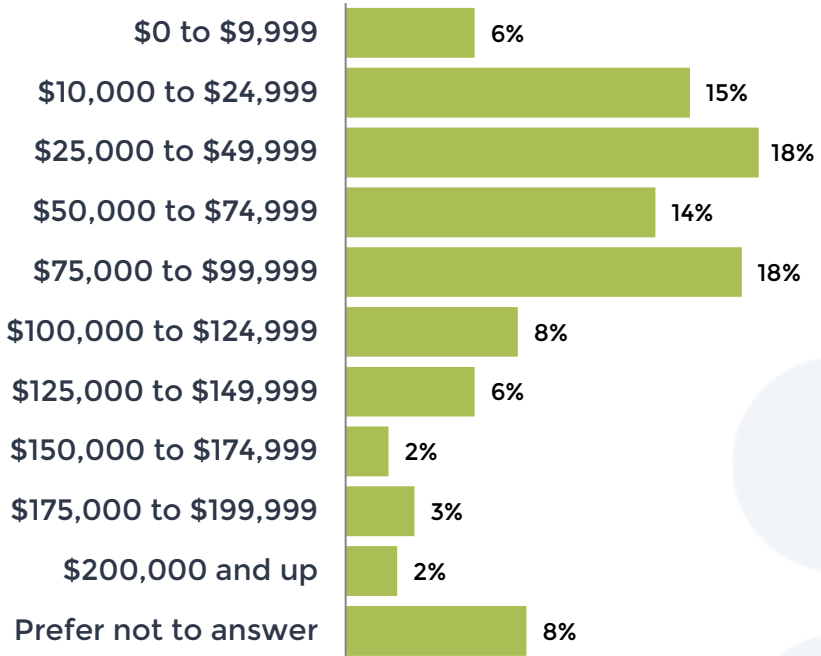
Patients: (n=632)

Caregivers: (n=224)

Household Income

Patients

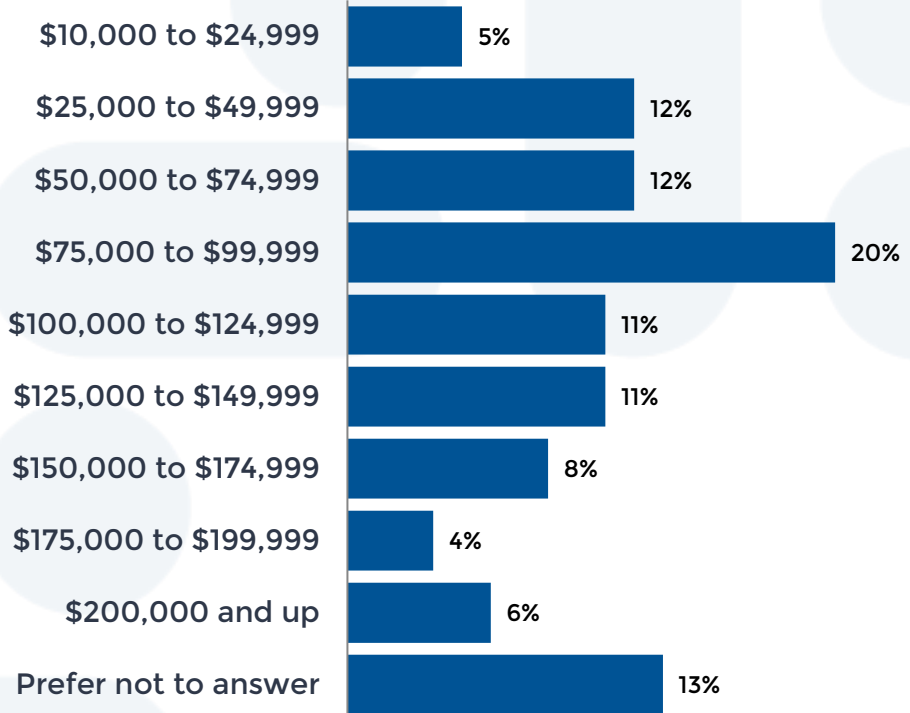
What was the total combined income for all members of your HOUSEHOLD in 2021, prior to taxes?



Patients: (n=632)

Caregivers

What was the total combined income for all members of your HOUSEHOLD in 2021, prior to taxes?



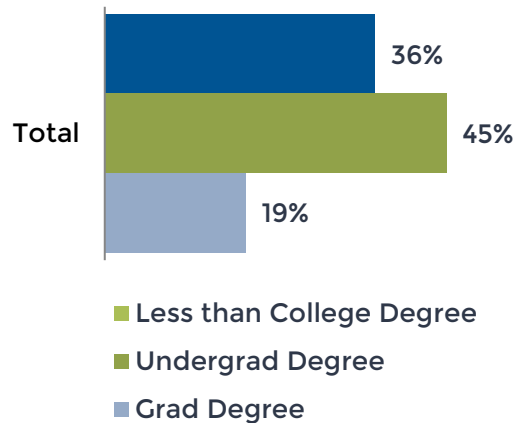
Caregivers: (n=224)

Education and Location

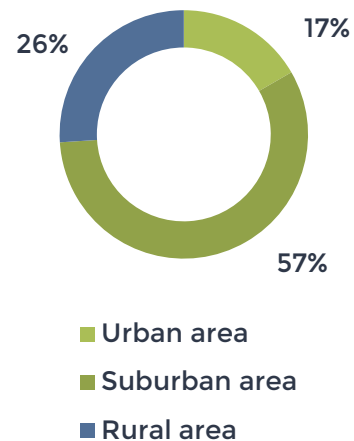
Patients

Caregivers

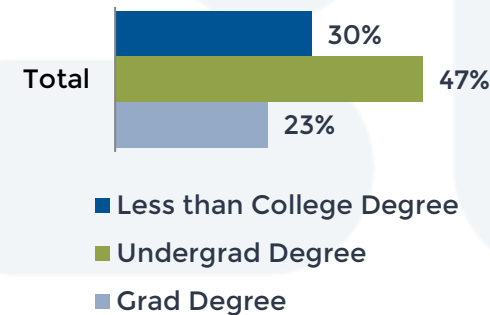
What is the highest degree or level of school you have completed?



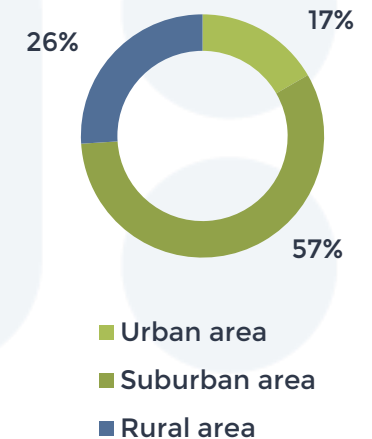
At that time, was your home in an:



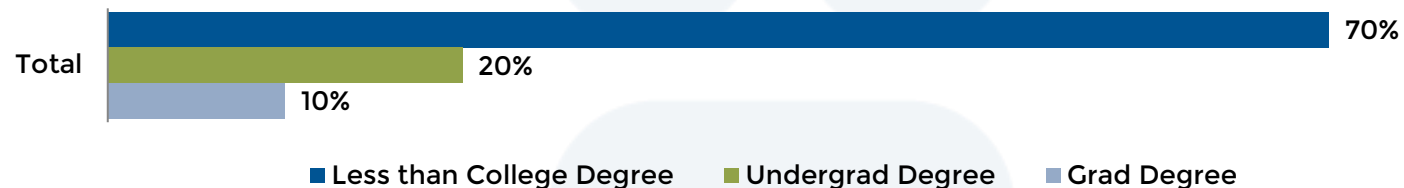
What is the highest degree or level of school you personally (not the person you care for) have completed?



At that time, was your home in an:



What is the highest degree or level of school the patient whom you care for has completed?



Patients: (n=632)

Caregivers: (n=224)

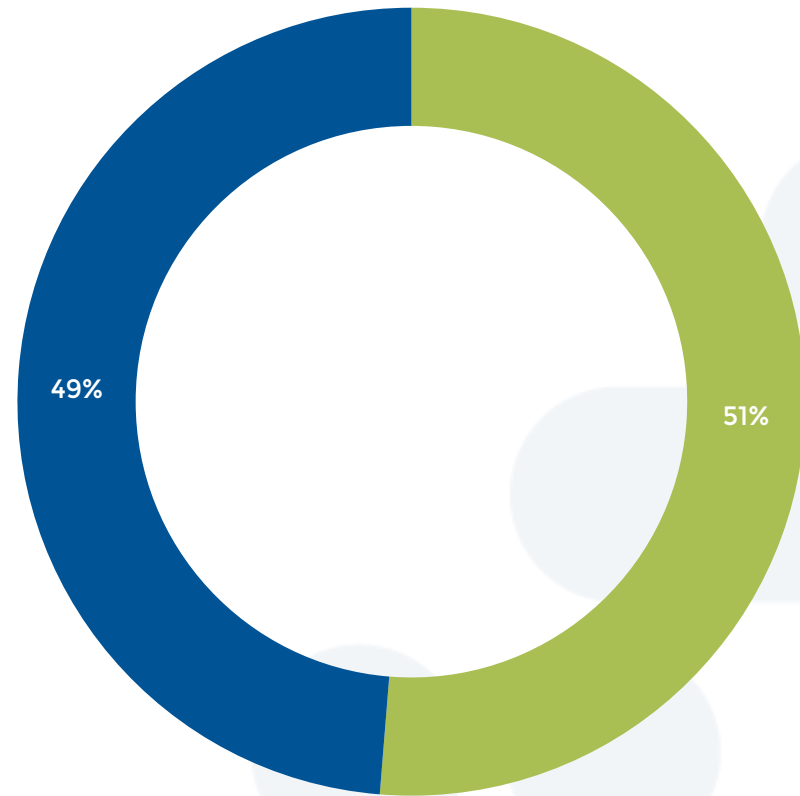


APPENDIX E

Part II: Quantitative Participant Demographics



Sample Size (n=117)

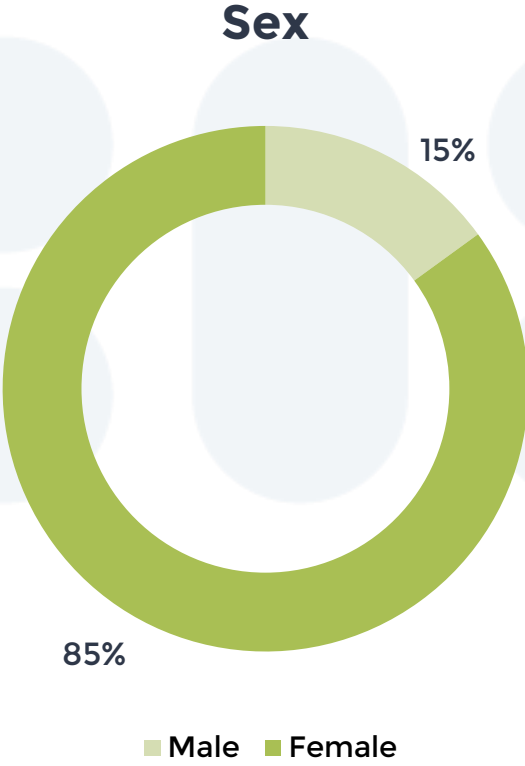
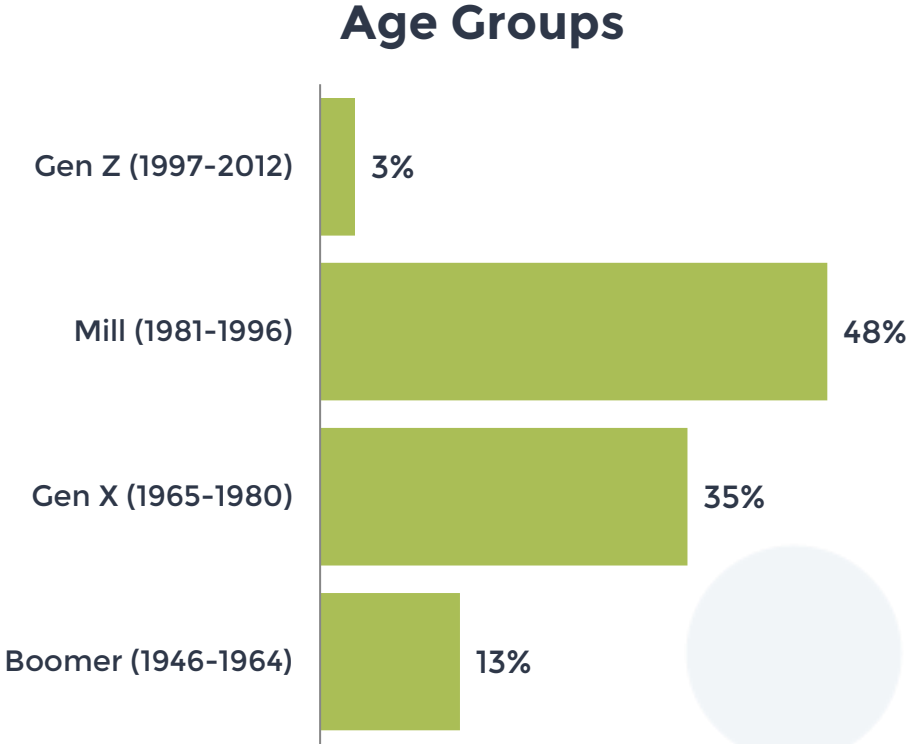


■ Patient ■ Caregiver

Patient (n=60)

Caregiver (n=57)

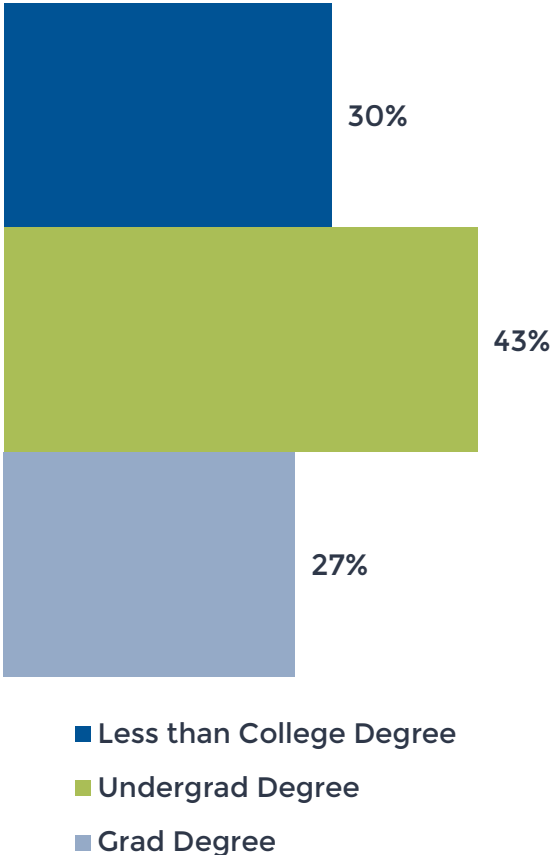
Demographics - Patient



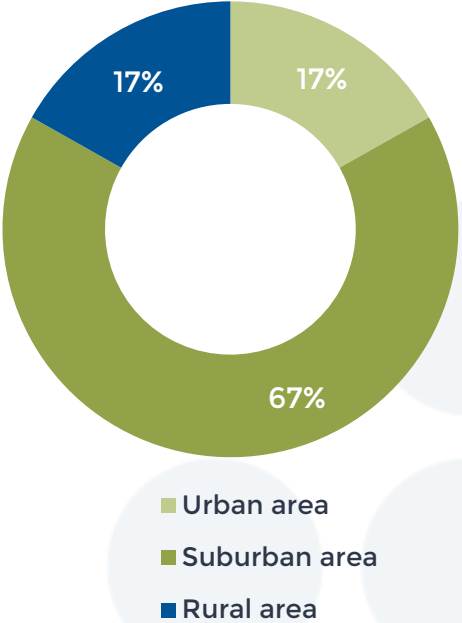
Patient (n=60)

Demographics - Patient

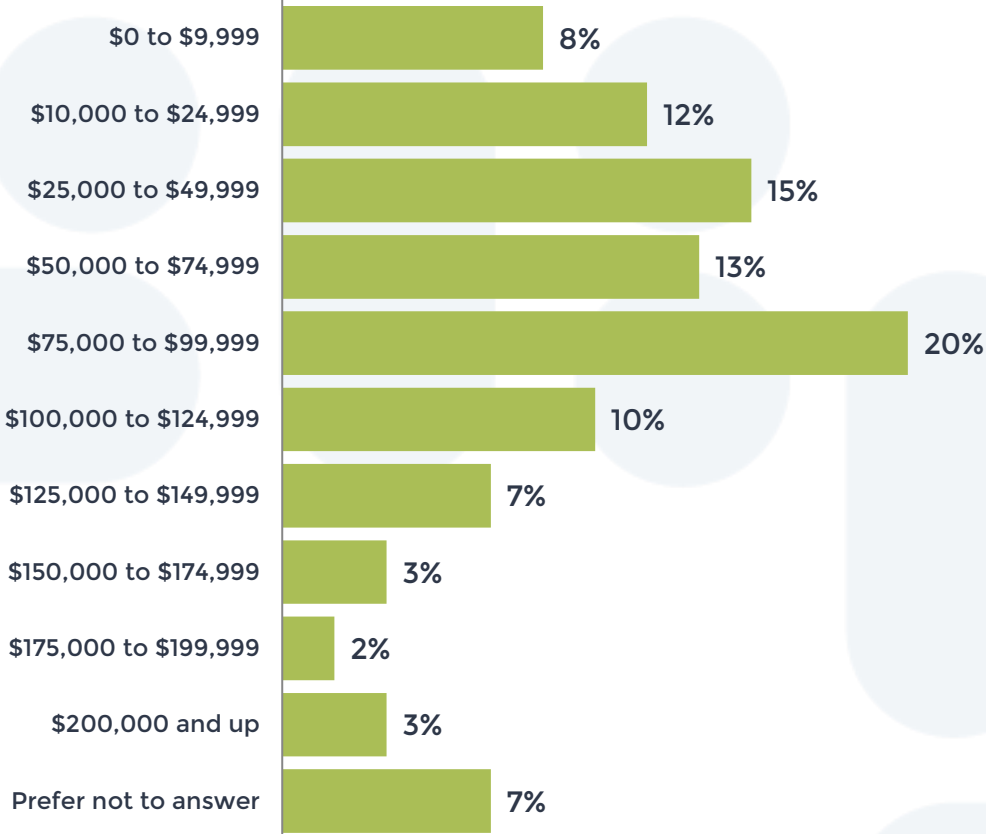
Education



Location



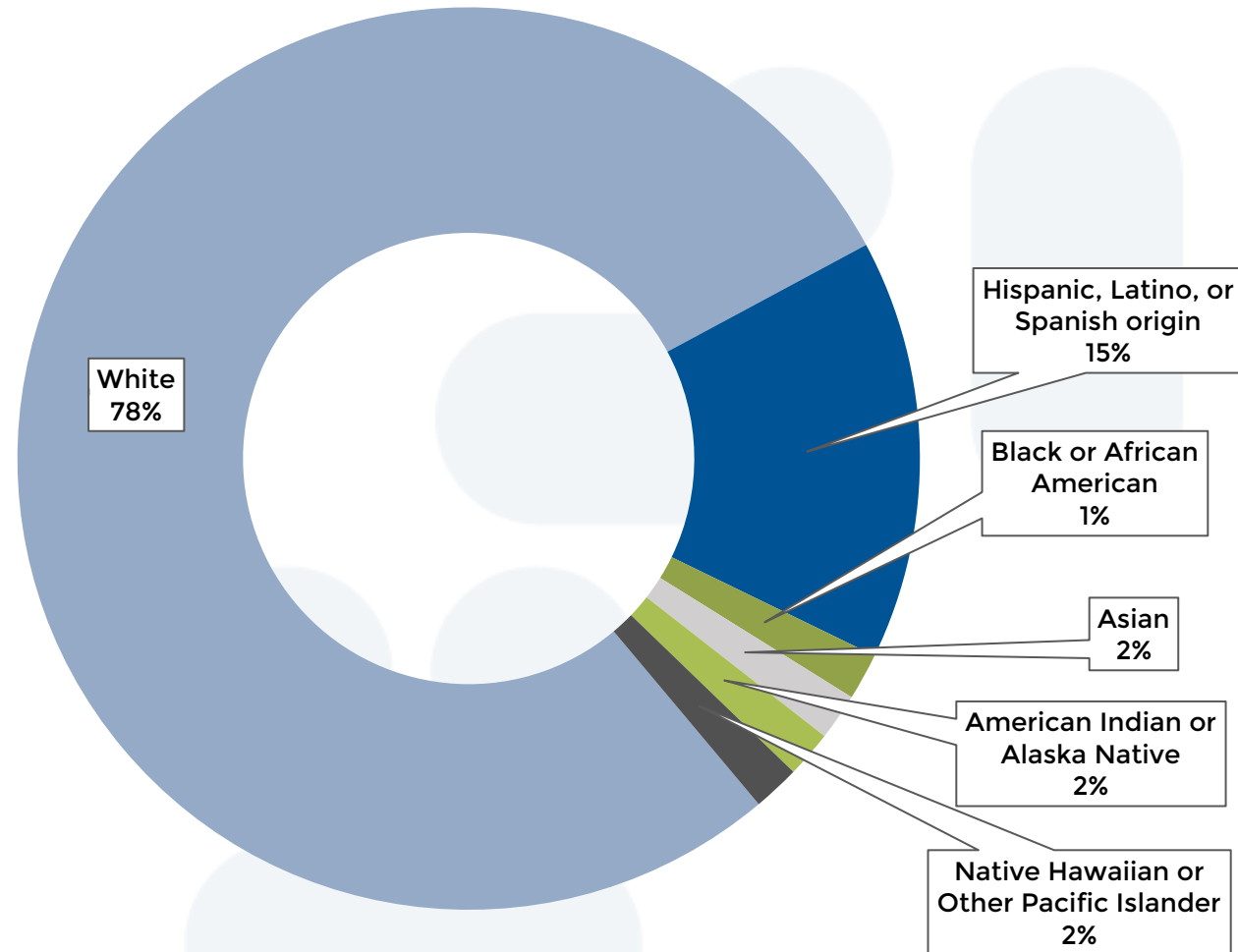
2021 Household Income



Patient (n=60)

Demographics – Patient

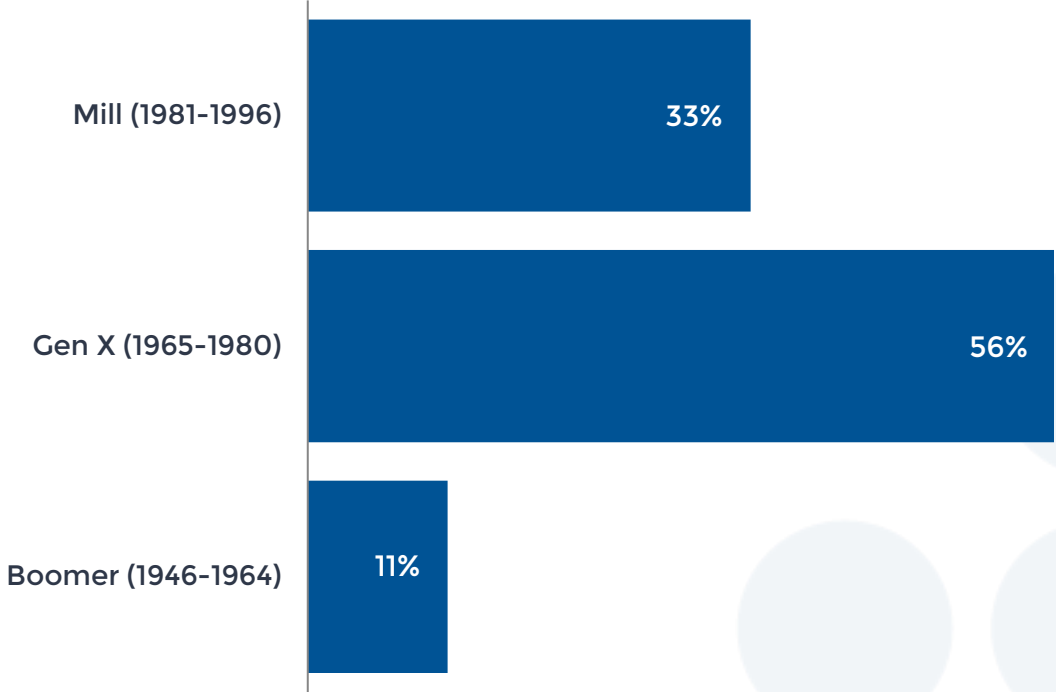
Ethnicity



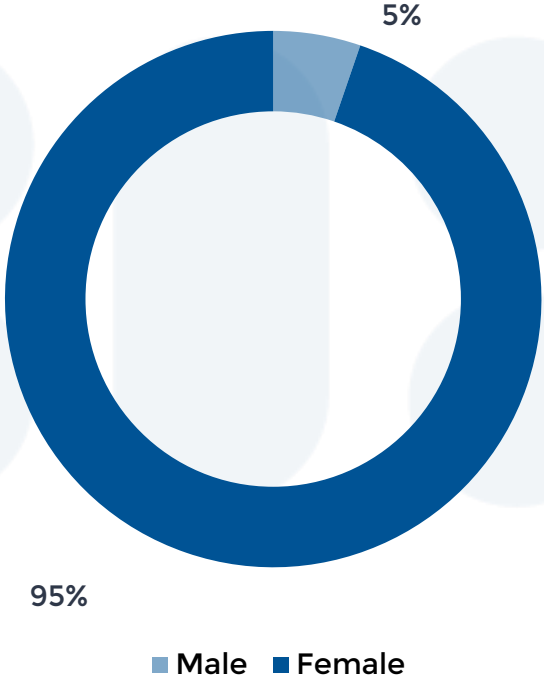
Patient (n=60)

Demographics - Caregiver

Age Groups



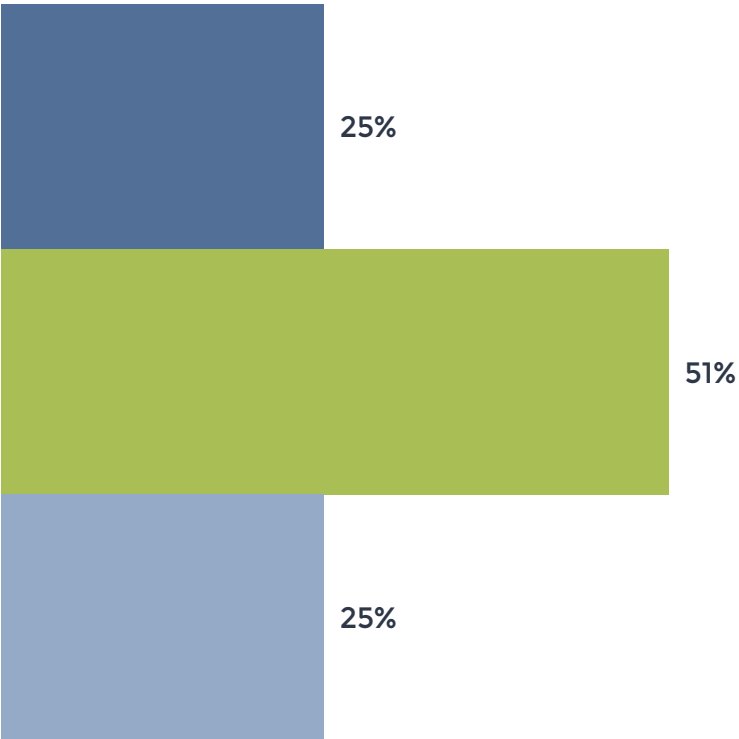
Sex



Caregiver (n=57)

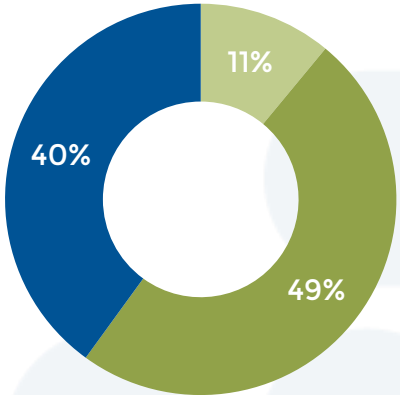
Demographics - Caregiver

Education



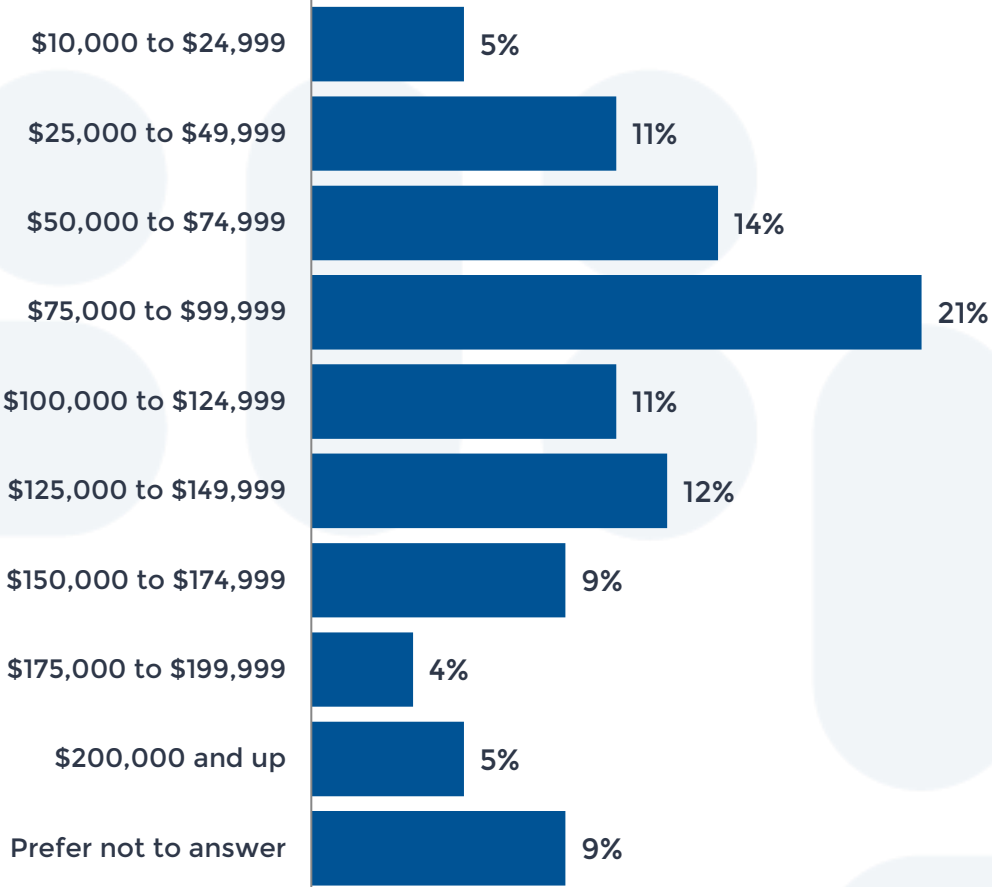
- Less than College Degree
- Undergrad Degree
- Grad Degree

Location



- Urban area
- Suburban area
- Rural area

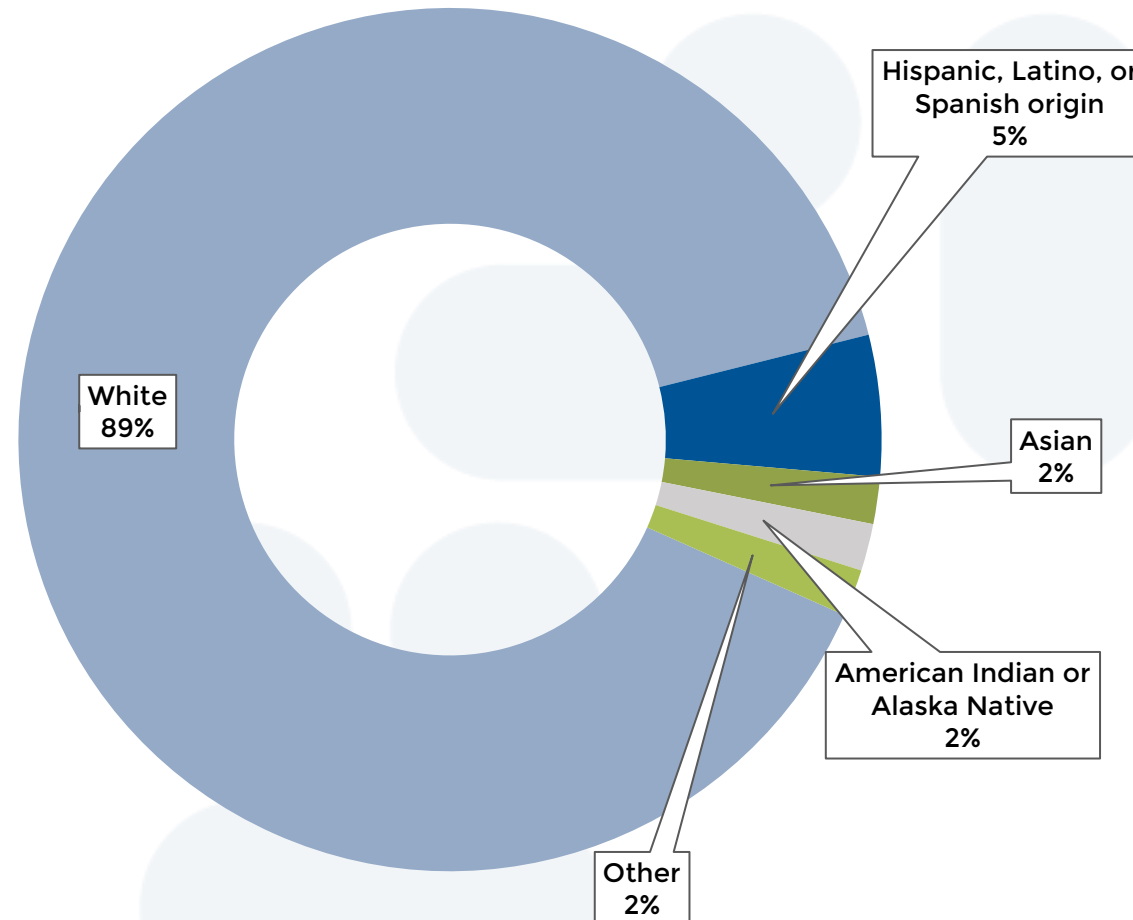
2021 Household Income



Caregiver (n=57)

Demographics – Caregiver

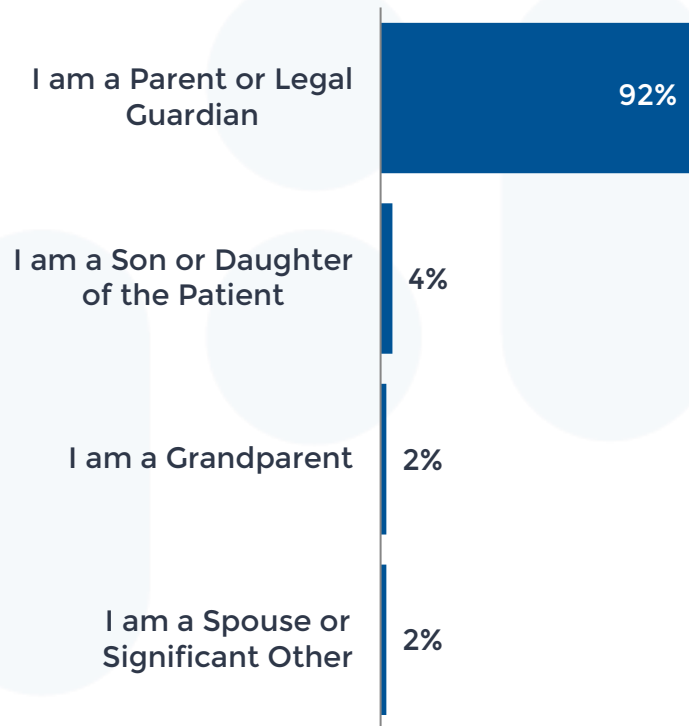
Ethnicity



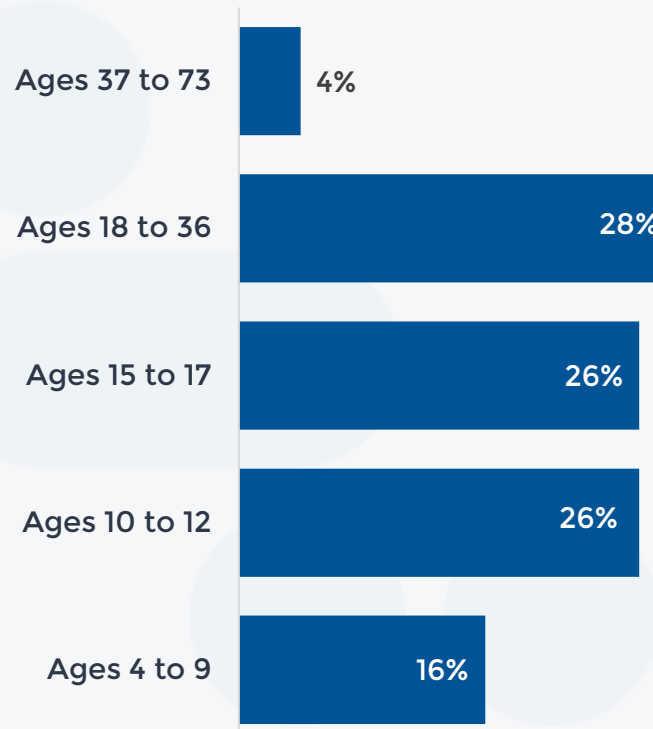
Caregiver (n=57)

Caregiver – Who do you care for?

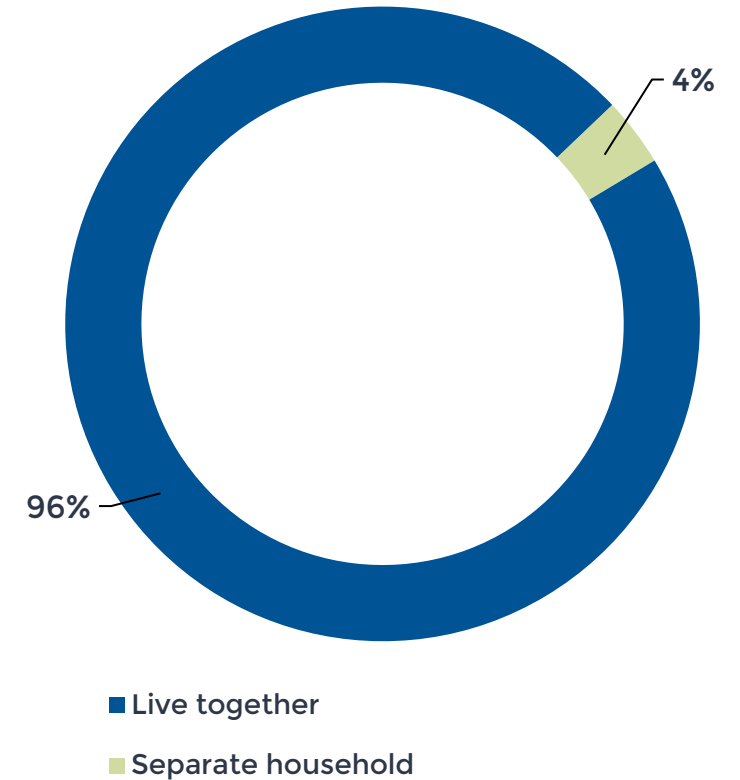
Relationship to the person you care for



Age of the person you care for



Living Arrangements



SECTION 10



Contact Information & About Us



Contact Information

For additional information or to discuss Clincierge's patient support solutions, please contact:

Pam Guthrie

Director of Client Strategy

Clincierge

Pamela.Guthrie@clincierge.com

About Clincierge

Clincierge reduces barriers to clinical trial participation by employing patient-centric strategies to enhance the patient experience, increase patient retention, and improve clinical trial performance. We provide personalized patient logistics management, travel, reimbursement, and convenience services to support clinical trial participants. This enables earlier client submissions with the potential of coming to market sooner and recovering R&D investments ahead of projections. Learn more at www.clincierge.com

About Insight & Measurement, LLC

David Harris, Founder, has over 20 years of experience in leadership in marketing research and organizational development. His passion is helping organizations get the information and insights needed for better decision-making. He is committed to building value for the organization through consulting, the application of thoughtful marketing research, training, and commitment to principles and goals. Learn more at www.imresearch.org

About Rare Patient Voice

Rare Patient Voice, LLC provides patients and caregivers with rare and non-rare diseases an opportunity to voice their opinions through surveys and interviews to improve medical products and services. Learn more at www.rarepatientvoice.com