

Opdualag™ Submission Survey Results Data

October 2023

Data gathered from the survey “The Patient Experience of Nivolumab + Relatlimab (Opdualag™),” developed by Save Your Skin Foundation for CADTH and INESSS submissions regarding Opdualag™ (Nivolumab + Relatlimab) as a treatment for adult cutaneous melanoma in stage III unresectable or stage IV melanoma



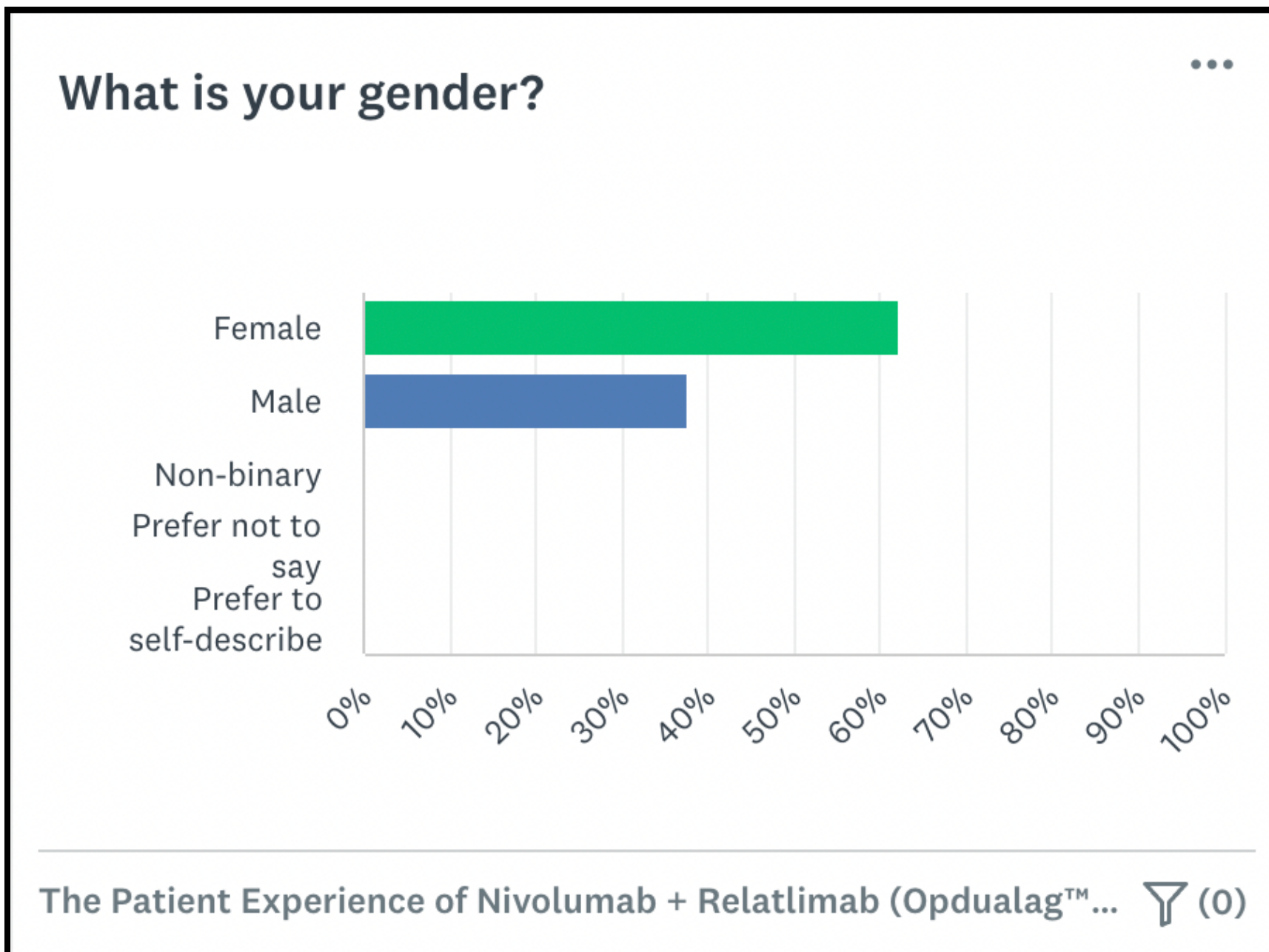
Save Your Skin Foundation developed this survey to gather patient experiences regarding the use of Opdualag™ as a treatment for adult cutaneous melanoma in stage III unresectable or stage IV melanoma. The survey was open to everyone who has received a treatment for melanoma, regardless of stage and experience with Opdualag™; however, data logic has been applied to ensure that only applicable participants answer the questions about Opdualag™. This information was used for Save Your Skin Foundation to prepare submissions for access to Opdualag™ to the Canadian Agency for Drugs and Technologies in Health (CADTH) and Institut national d'excellence en santé et en services sociaux (INESSS).

Two versions of the survey were open from July 3–July 15, one in English and one in French. Data from both of the surveys was combined for the aforementioned CADTH and INESSS submissions. For this presentation, visual representations of the English results will be accompanied by description of the French data for each question.



Survey Demographics:

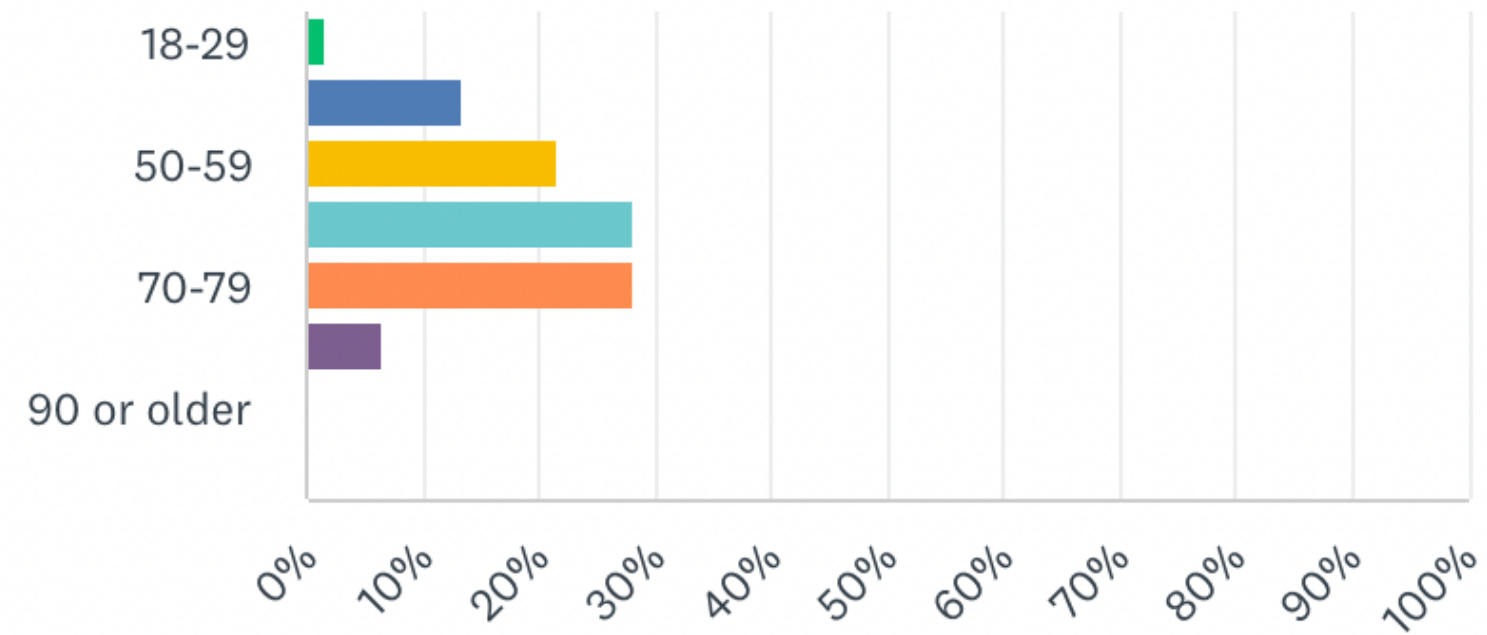
Questions 1-5



Question 1: Gender Identification

In the French language survey, 85.71% of participants identified as female and 14.29% as male.

What is your age?

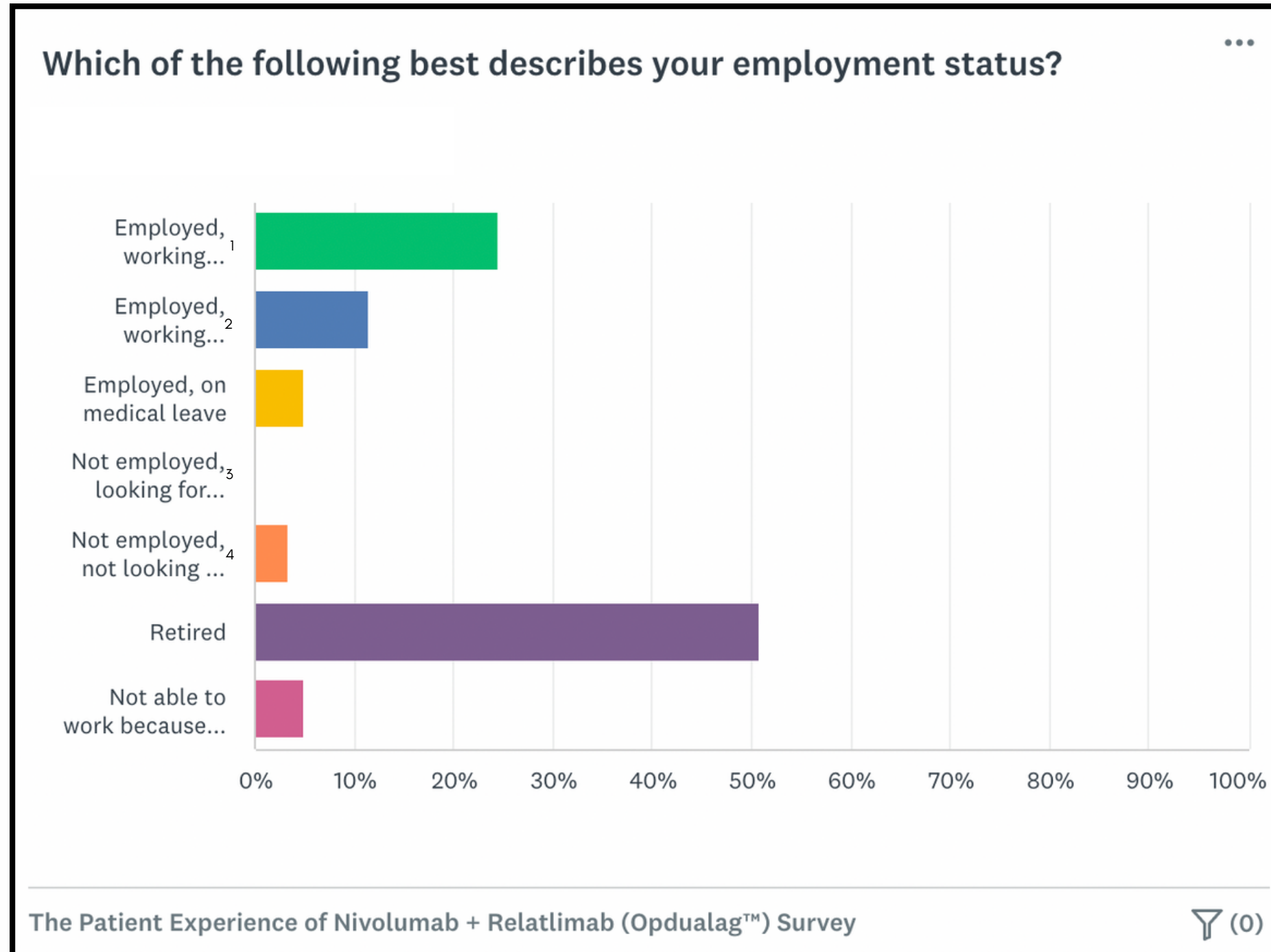


The Patient Experience of Nivolumab + Relatlimab (Opdualag™... (0)

Question 2: Age

57.14% of French language survey participants were between ages 30–49, 28.57% between 70–79, and 14.25% between 60–69.

Question 3: What Best Describes your Employment Status?



1. Employed, working full-time
2. Employed, working part-time
3. Not employed, looking for work
4. Not employed, not looking for work

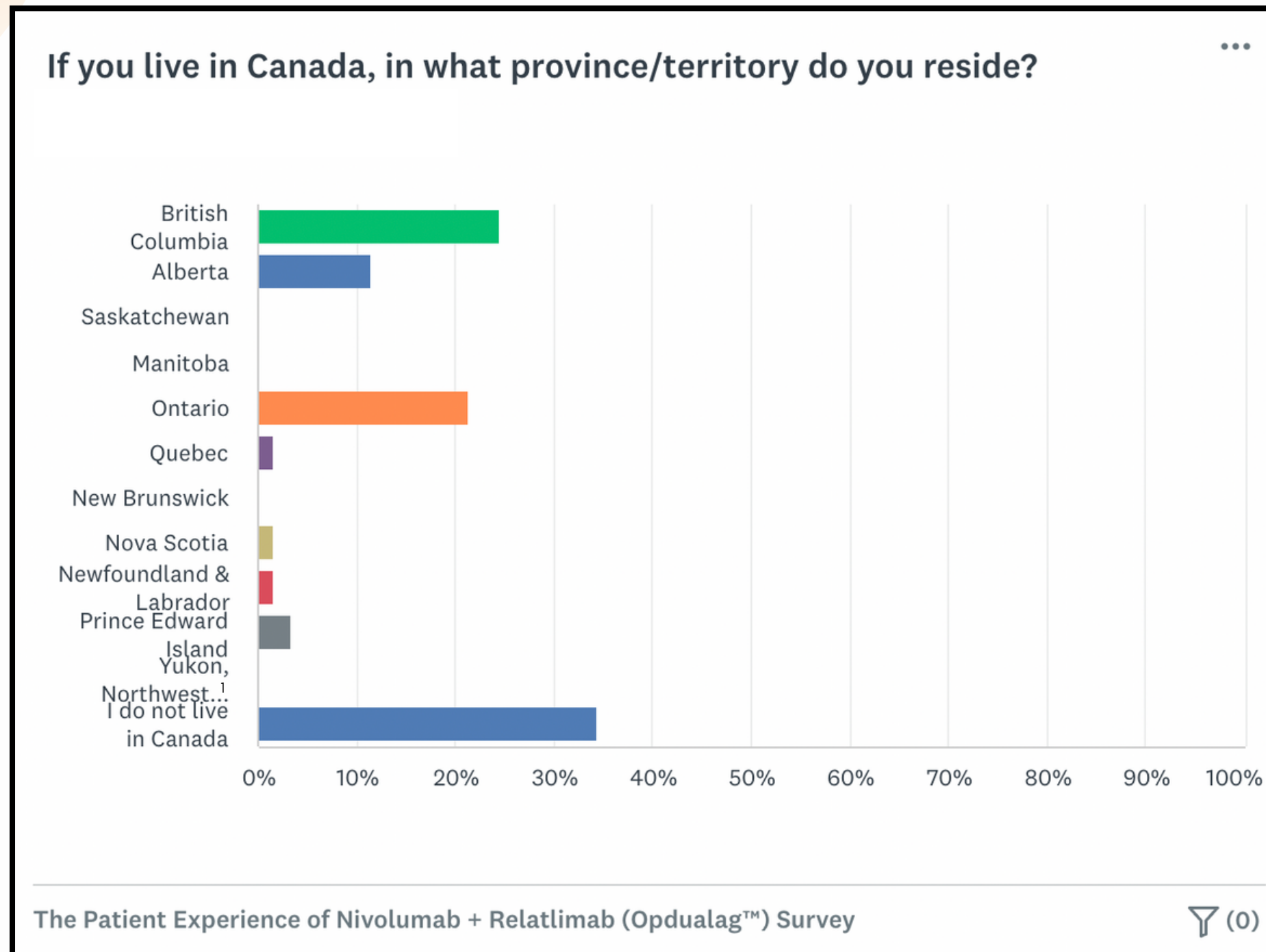
In question 3 of the French language survey, 28.57% of the participants are working full time, while another 28.57% are unable to work due to health-related reasons. The remaining 42.86% are retired.

Question 4: If you Live in Canada, in What Province/Territory do you Reside?

1: Yukon, Northwest Territory, or Nunavut

In question 4 of the French language survey, 100% of the participants reside in Quebec, other than the 1 participant who indicated in question 5 that they are in France.

In question 5, which asked participants where they were from if not Canada, all indicated that they were from the United States except for 1 participant from Australia.

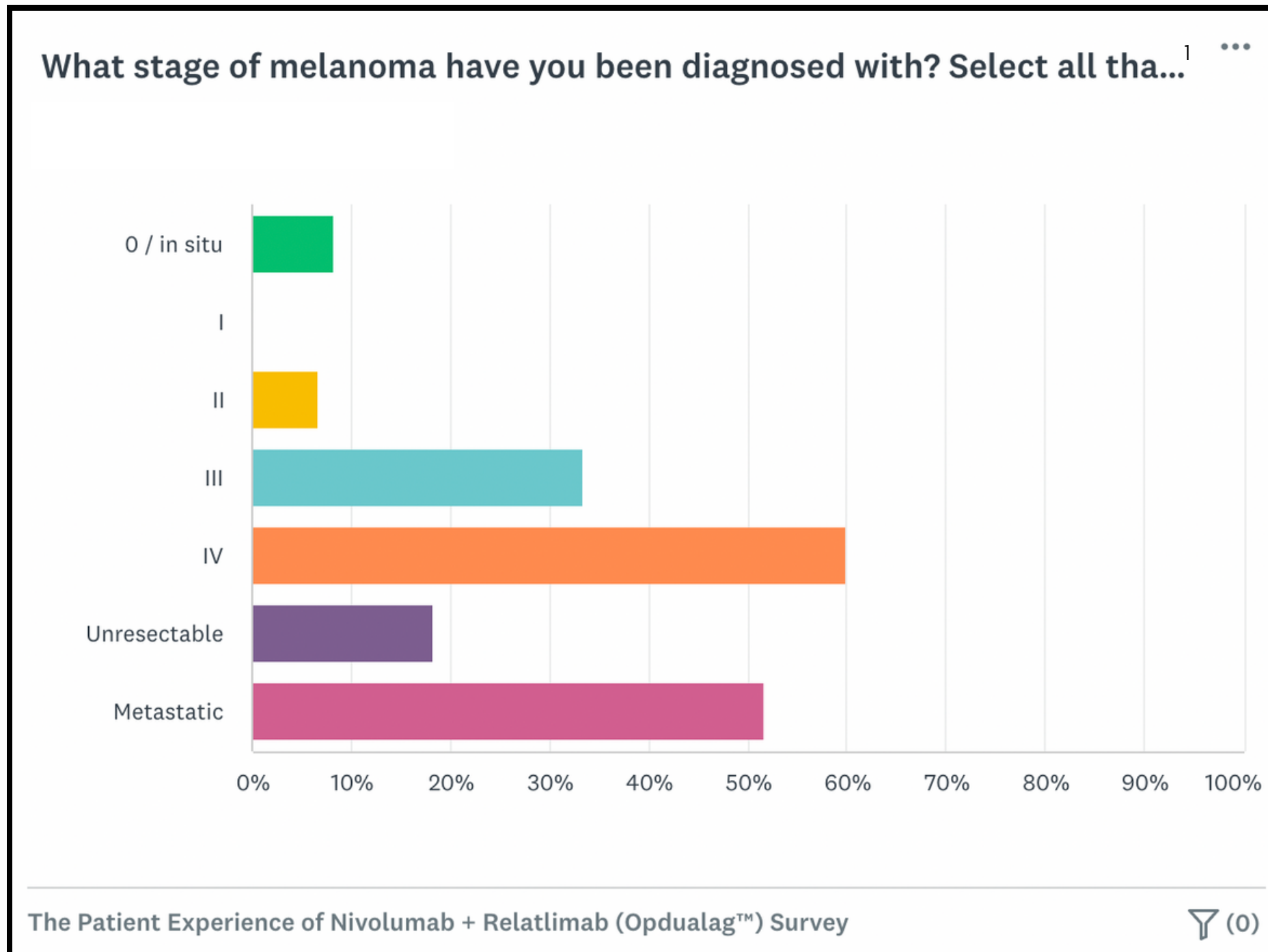




Participant Melanoma Information: Questions 6-9

Question 6: (1) What stage of melanoma have you been diagnosed with? Select all that apply. Please also select whether the descriptors “unresectable” or “metastatic” apply to your melanoma.

In the French language survey, 16.67% of participants have stage II melanoma, 66.67% stage III, and 16.67% stage IV. 16.67% indicated that their melanoma was unresectable.



Question 7: Year of Melanoma Diagnosis

Survey participants across both the English and French language surveys indicated being diagnosed with melanoma in the following years. The percentage listed for each year combines the English and French surveys.

- 2022 (20%)
- 2019 (15%)
- 2020 (11.66%)
- 2017 (8.33%)
- 2021 (8.33%)
- 2010 (6.66%)
- 2023 (5%)
- 2016 (5%)
- 2013 (5%)
- 2018 (5%)
- 2015 (3.33%)
- 2003 (3.33%)
- 2012 (1.66%)



Question 8: What has been your experience with this type of cancer? For example, physical, mental, financial, emotional toll etc.

Survey participants across both the English and French language surveys listed the following as physical, mental, and emotional affects of their melanoma diagnosis and experience. The following is a selection of the comments offered by participants.

- Great emotional toll (several)
- Physical exhaustion (several)
- Mental exhaustion (several)
- Financial burden (several)
- Severe side effects from treatment (some)
- Anxiety about future (some)
- Scary (some)
- Amazing healthcare team (some)
- Strain on family relationships (some)
- Fear of death (some)
- Depression (some)
- Life altering (some)
- Had to travel for care (a few)
- Needed to self-advocate (a few)
- Tired of waiting for test results (a few)

Question 9: Do you have any ongoing symptoms with this type of cancer? If yes, please list them.

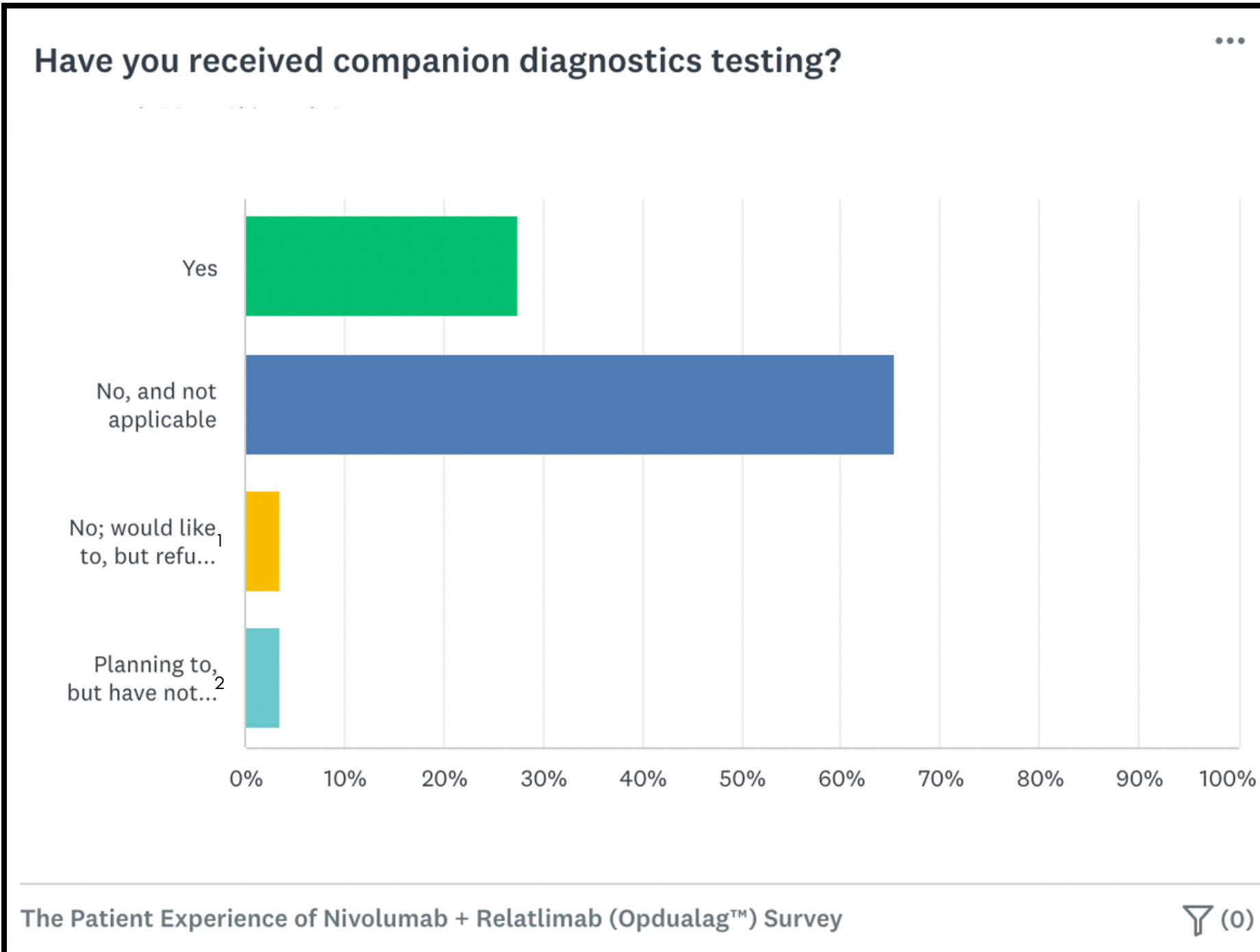
Survey participants across both the English and French language surveys listed the following as ongoing symptoms of their cancer experience. The following is a selection of the comments offered by participants.

- No ongoing symptoms (several)
- Fatigue (several)
- Skin sensitivities/problems (some)
- Extreme pain (some)
- Hypothyroidism (a few)
- Limited mobility (a few)
- Weight gain (a few)
- Swelling (a few)
- Numbness (a few)
- Impaired vision (a few)
- Lost sense of taste/smell (a few)
- Joint pain (some)
- Abdominal pains (some)
- Brain fog (a few)
- Migraines (a few)
- Loss of vision (a few)
- Difficulty with mouth functions (eating and speaking) (a few)

Companion Diagnostics

Testing:

Questions 10-20



Question 10: Have you Received Companion Diagnostics Testing?

(1) No; would like, but refused by doctor

(2) Planning to, but have not received it yet

66.67% of French language participants indicated that they have not received companion diagnostics testing and the question is not applicable to them; 16.67% have received companion diagnostics testing; and 16.67% would have liked to receive companion diagnostics testing but were refused by their doctor.

Question 11: Did you face any challenges in accessing testing or booking the appointment?

Across both the English and French language survey, no participants who received companion diagnostic testing reported having difficulties with accessing the testing. Please bear in mind that the participant population for this question has successfully received companion diagnostics testing.

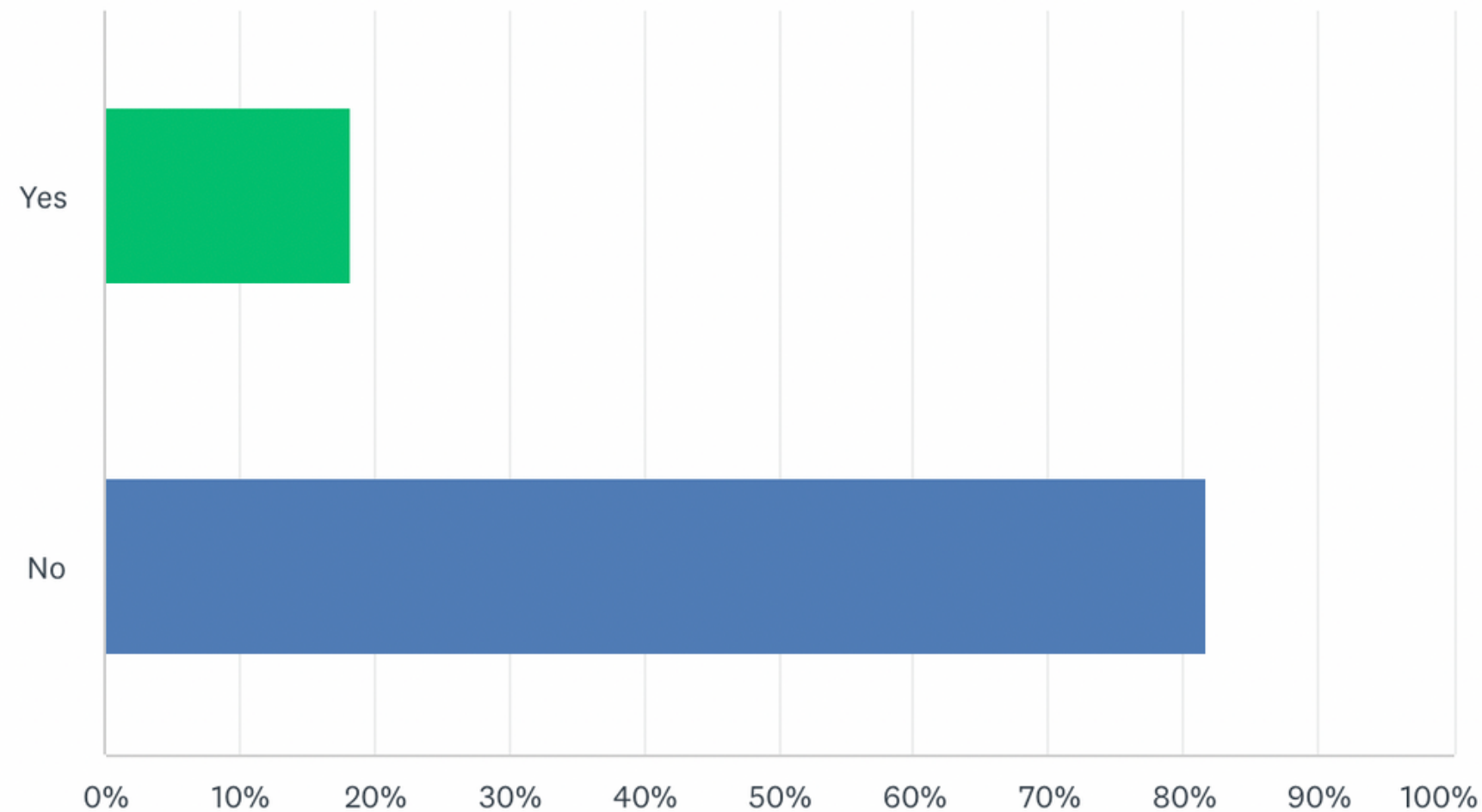


Question 12: How was the companion diagnostics test conducted?

Across the English and French language surveys, participants described the delivery of their companion diagnostics testing as an even distribution of skin biopsies, tumour biopsies, CT scans, and bloodwork.



Did the testing process cause any delays in starting your treatment?



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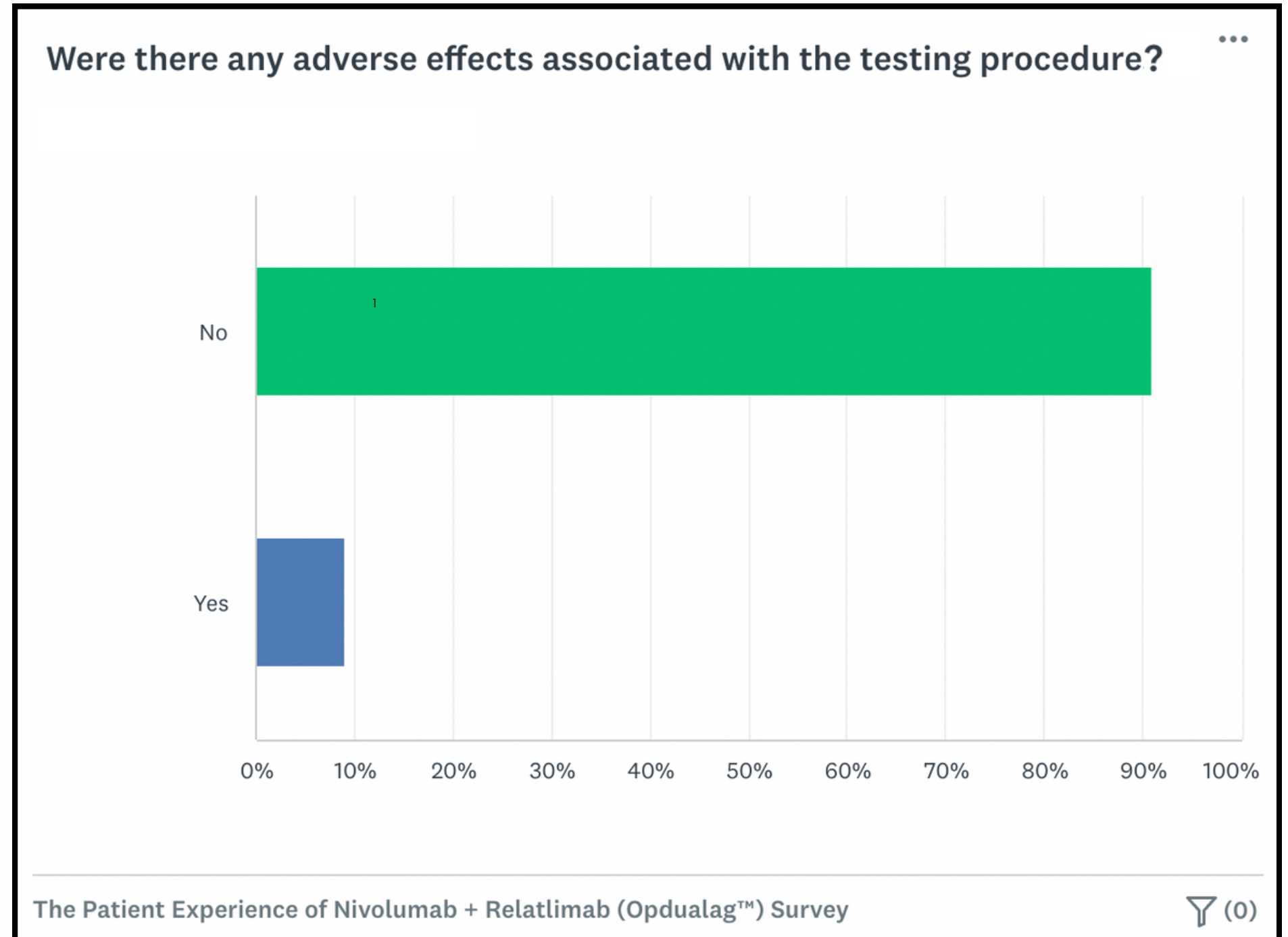
Question 13: Did the testing process cause any delays in starting your treatment?

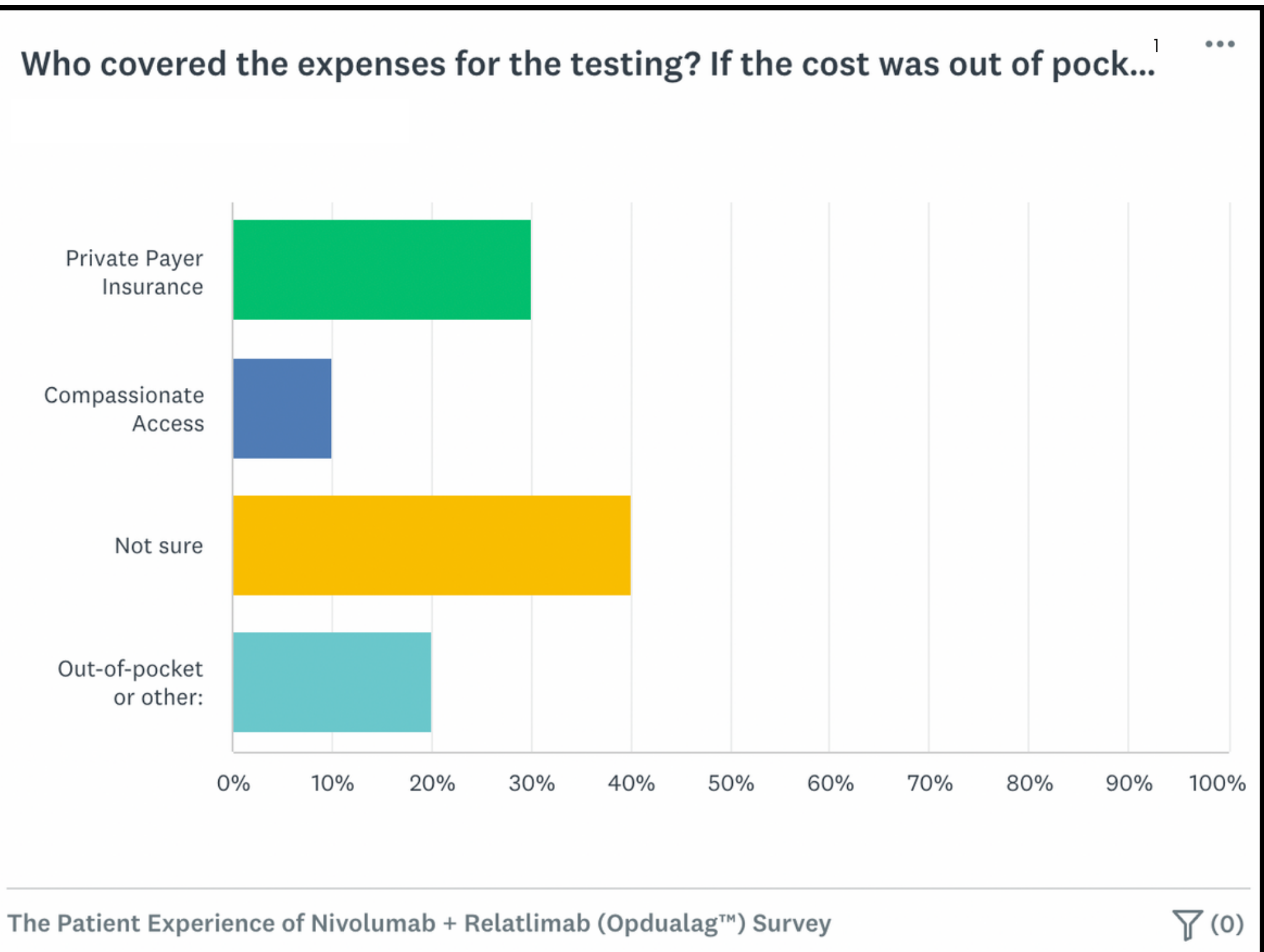
100% of French language participants indicated that companion diagnostics testing did not delay the start of their treatment.

Question 14: Were there any adverse effects associated with the testing procedure?

100% of the French language participants indicated that there were no adverse events associated with their companion diagnostics testing.

Additional comments by participants on this question included noting a delay in test results.





Question 15: (1) Who covered the expenses for the testing? If the cost was out of pocket, what impact did it have?

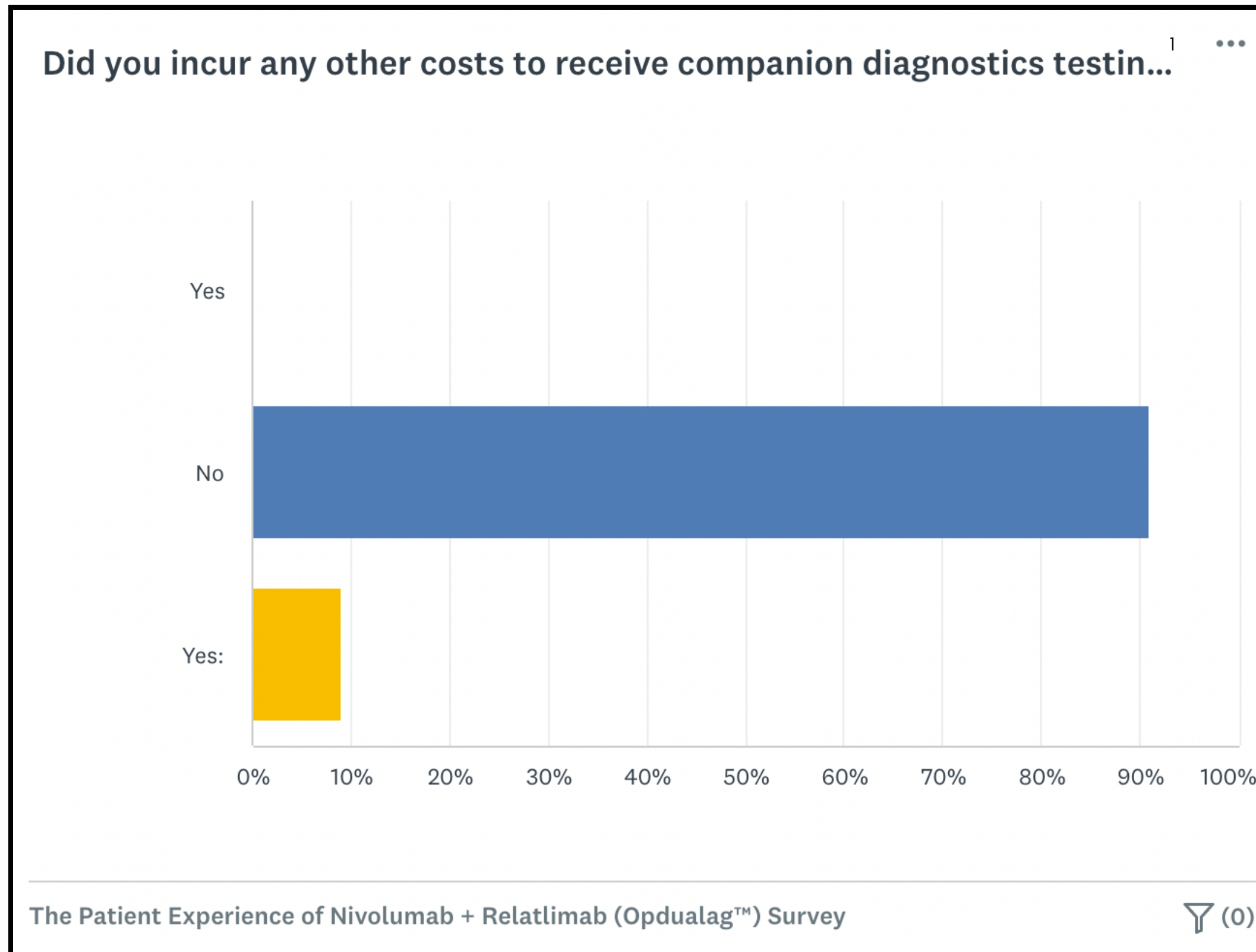
100% of the French language participants had the expenses of their companion diagnostics testing covered through compassionate access.

Unfortunately, we were not offered any additional details by participants who covered their own testing costs.

Question 16: (1) Did you incur any other costs to receive companion diagnostics testing?

0% of the French language participants incurred costs related to companion diagnostics testing.

Unfortunately, we did not receive any additional details about costs incurred for testing.



Question 17: How did you feel about undergoing the testing?

Across both English and French language surveys:

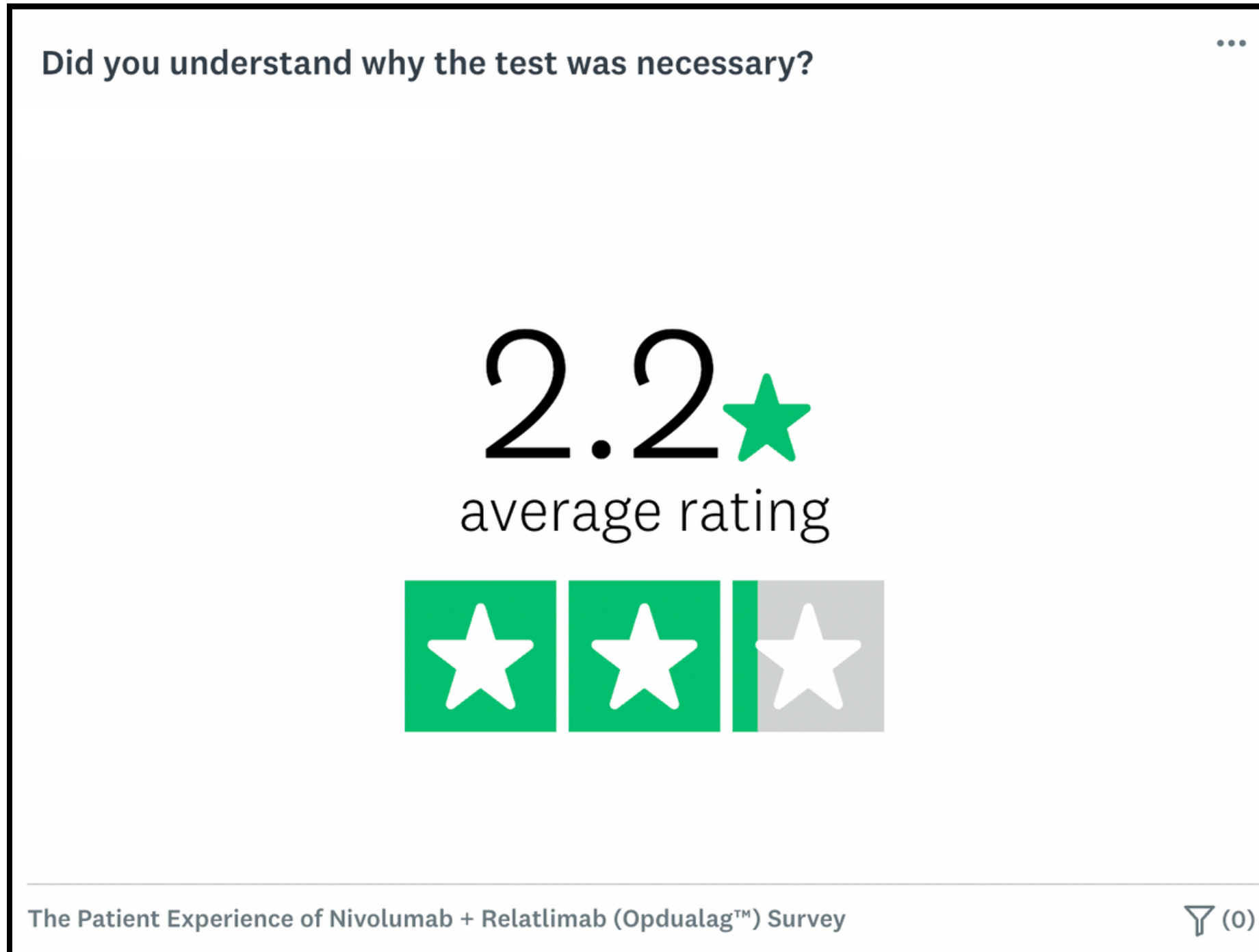
- Most participants were neutral about receiving the test
- Some participants acknowledged that the test was important to developing their care plan and were grateful to their healthcare team for suggesting it
- A few responses indicated nervousness surrounding the test

"Great. I knew they would do everything possible for me and I wanted wholistic, comprehensive testing."

"Grateful that it was available to me."

"Testing was completed after the tumor excision so no impact on myself."

Question 18: Did you understand why the test was necessary?



This question asked participants to rank their understanding of why they received companion diagnostics testing on a scale from 1-3. 1 indicated that they did not understand why they were receiving the test and/or did not have it explained to them; 2 mostly understood why they were receiving the test, but still had some questions; and 3 indicated that they completely understood why companion diagnostics tests were necessary. The 2.2 average rating was the average of 36.36% voting they did not understand why they were having it/it was not explained to them, 9.09% voting that they understood but still had some questions, and 54.55% completely understanding why they were receiving the test.

The French language survey participants had a score of 3, with 100% voting that they completely understood why they were receiving the test.

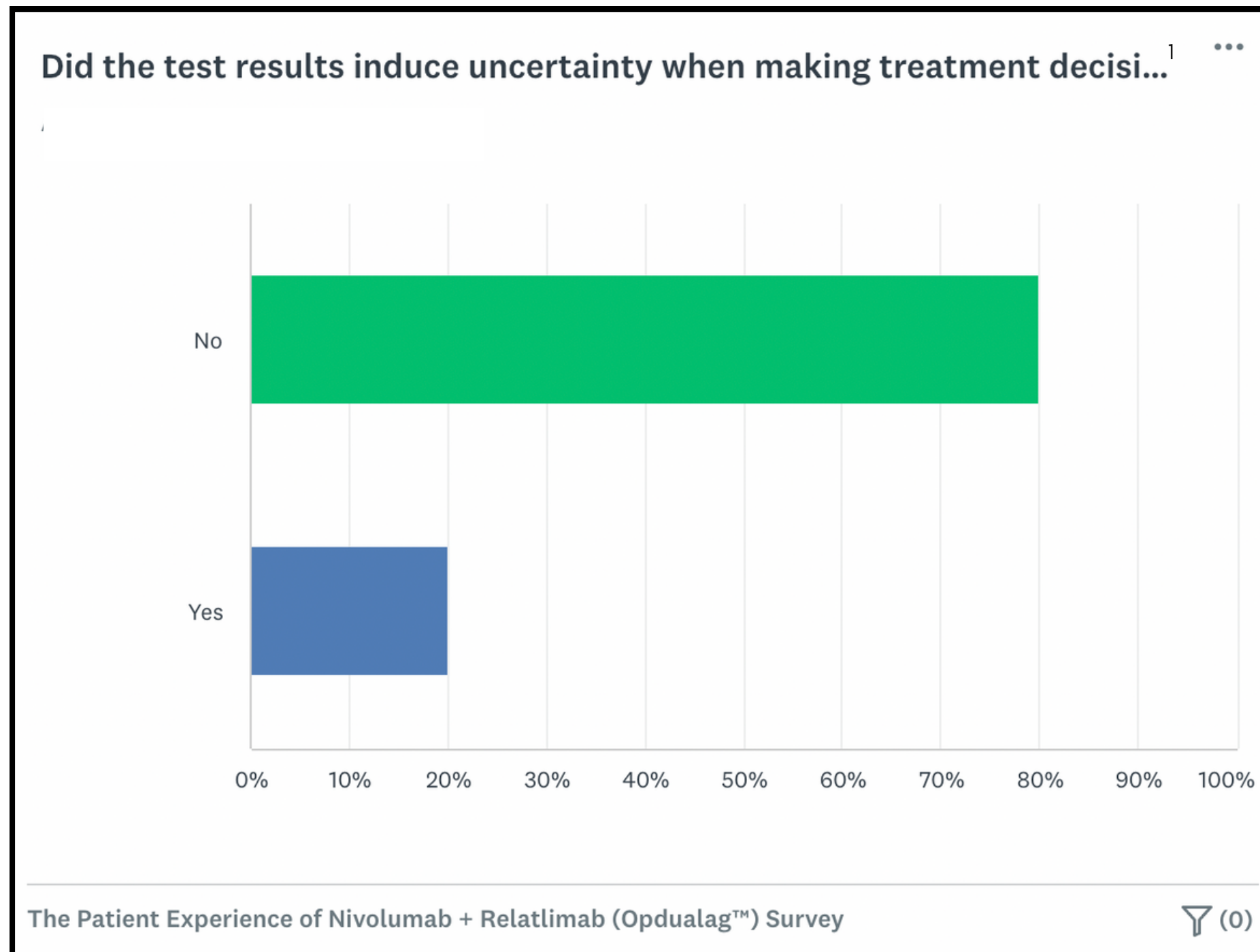
Question 19: How did you cope with anxiety while awaiting the test results?

Across both English and French language surveys:

- The responses were evenly split between having anxiety around these test results and not feeling stress
- One participant noted that their provider prescribed them Xanax to help them cope with their cancer-related anxiety



Question 20: (1) Did the test results induce uncertainty when making treatment decisions?



Question 18 asked whether the results from the companion diagnostics testing caused uncertainty in treatment-decision making. One participant commented that because they were BRAF positive they had to choose between immunotherapy types, which likely accounts for at least one 'yes' vote. 100% of the French language survey participants voted that undergoing companion diagnostics testing did not induce uncertainty when making their treatment plan.

Opdualag™ Data Collection

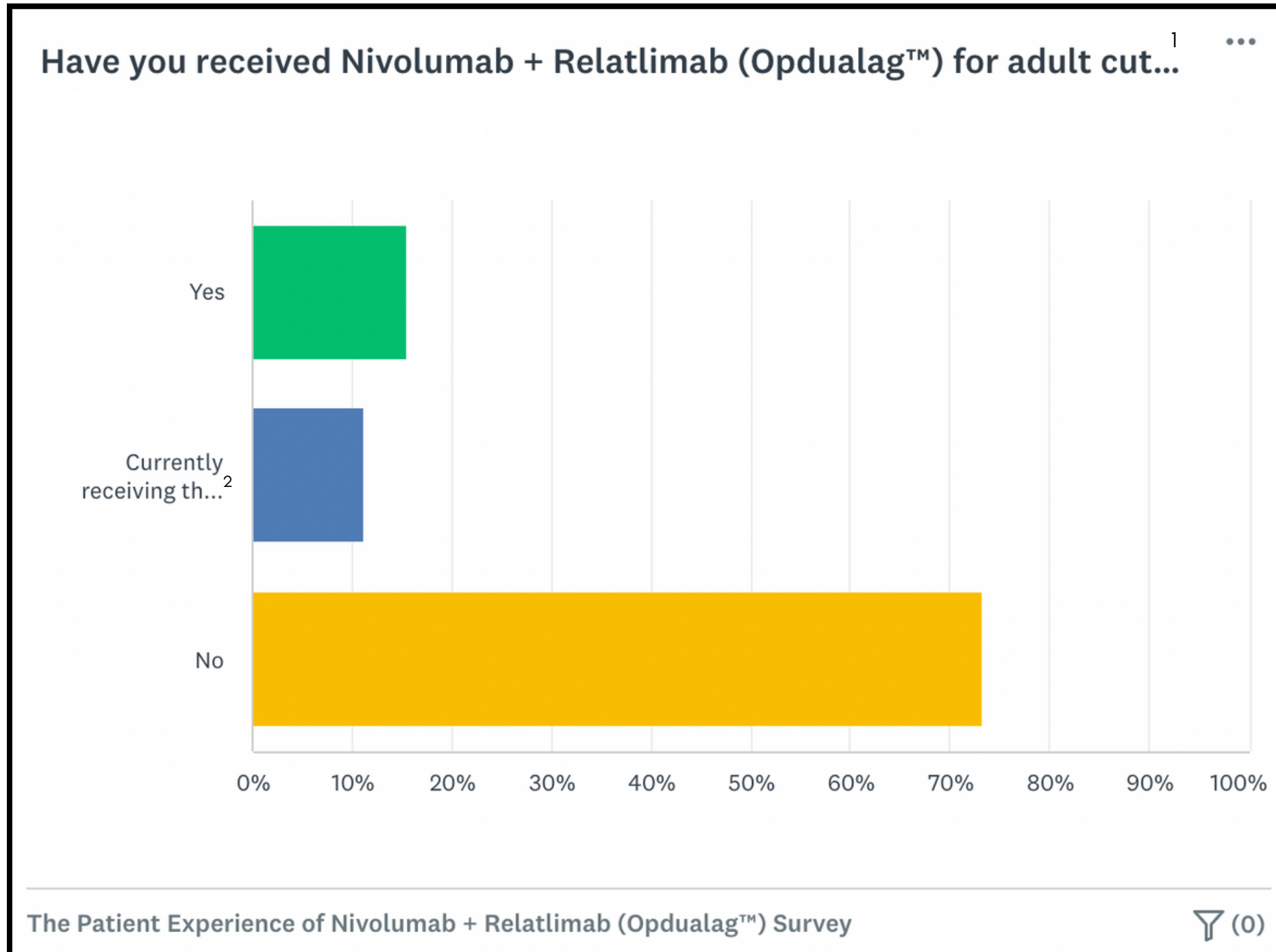
Question 36

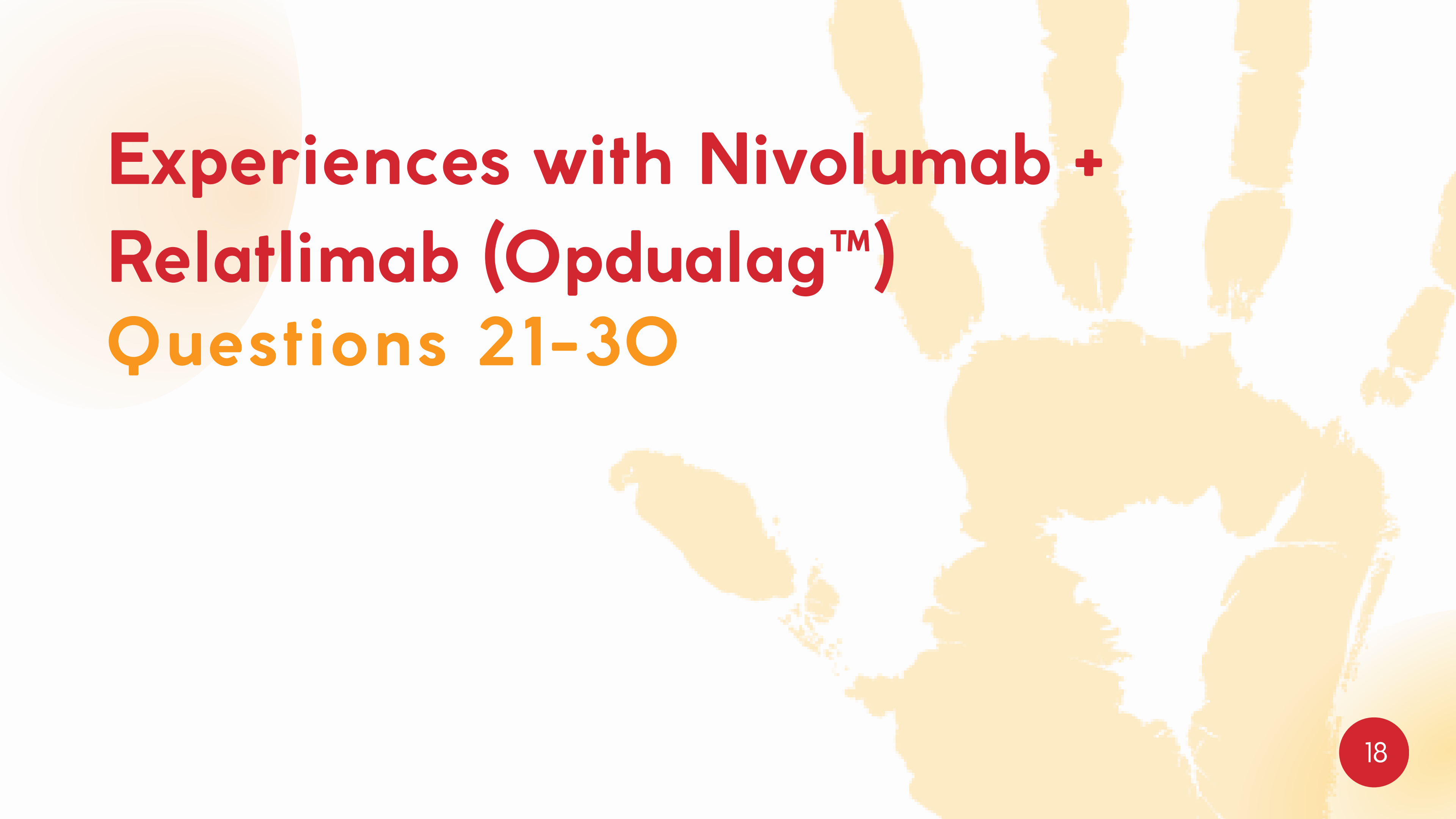
Please note that the logic sequence of the survey assigned “have you received Nivolumab + Relatlimab (Opdualag™) for adult cutaneous melanoma in stage III unresectable or stage IV melanoma?” was question 36 in this survey. To participants, it actually appeared after the companion diagnostics testing section and before the Opdualag™ section. Participants who indicated that they have not received Opdualag™ were logic skipped past those questions to the end of the survey, ensuring an undiluted data pool of participants who have received Opdualag™.

Question 36: (1) Have you received Nivolumab + Relatlimab (Opdualag™) for adult cutaneous melanoma in stage III unresectable or stage IV melanoma?

(2) Currently receiving this treatment

In the French language survey, 83.33% of participants have not received Opdualag™, while 16.67% were currently receiving Opdualag™ at the time of the survey.



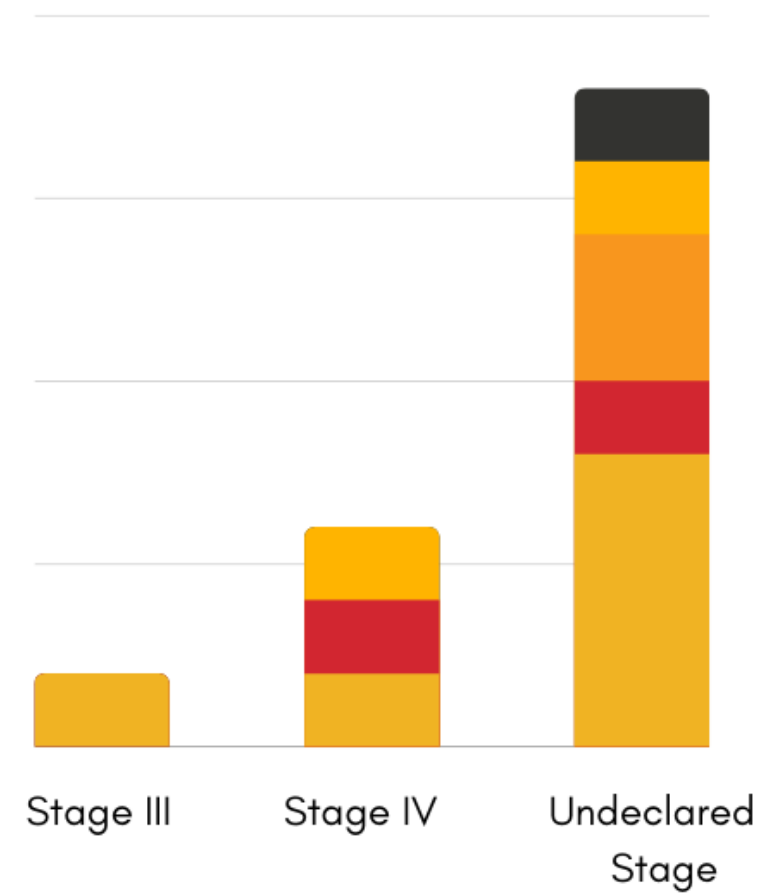


**Experiences with Nivolumab +
Relatlimab (Opdualag™)**
Questions 21-30

Question 21: Prior to receiving Nivolumab + Relatlimab (Opdualag™), had you received other treatment for melanoma? If so, what treatment and at [what] stage?

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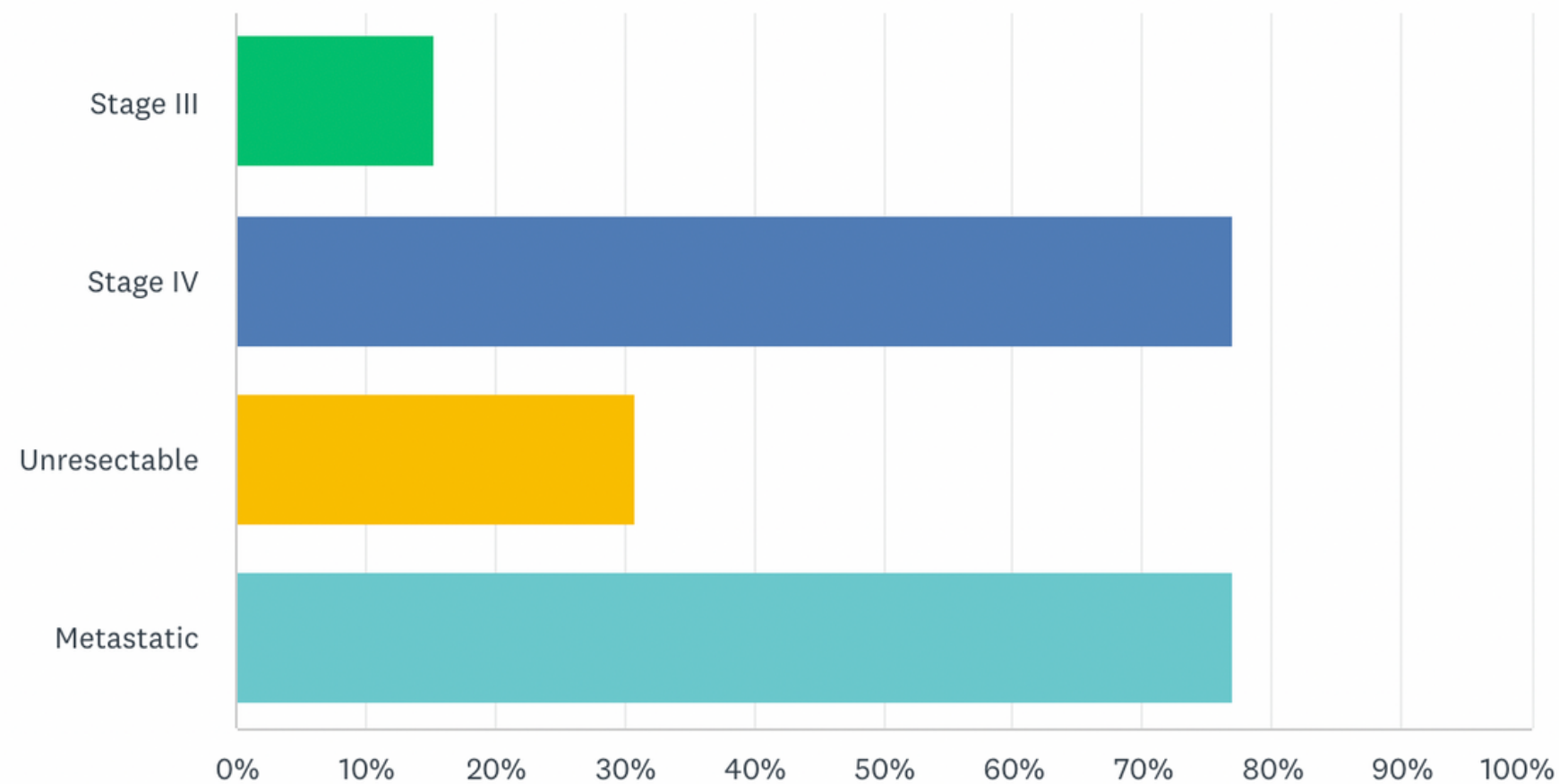
- 1
 - 2
 - 3
 - 4
 - 5
- Immunotherapy
 - Targeted Therapy
 - Chemotherapy
 - Surgery
 - Radiation



This graph combines the English and French language data regarding previous treatment for melanoma.

The majority of participants did not specify at which stage they received treatment for melanoma other than Opdualag™, likely because it is consistent with the stage of melanoma stage at which they were diagnosed and reported earlier in the survey. The most frequently cited type of treatment received other than Opdualag™ was immunotherapy, with Opdivo®, Yervoy®, Mektovi®, Braftovi®, and Mekinist®.

Under what cancer stage and type context did you receive Nivolumab ...¹ ...

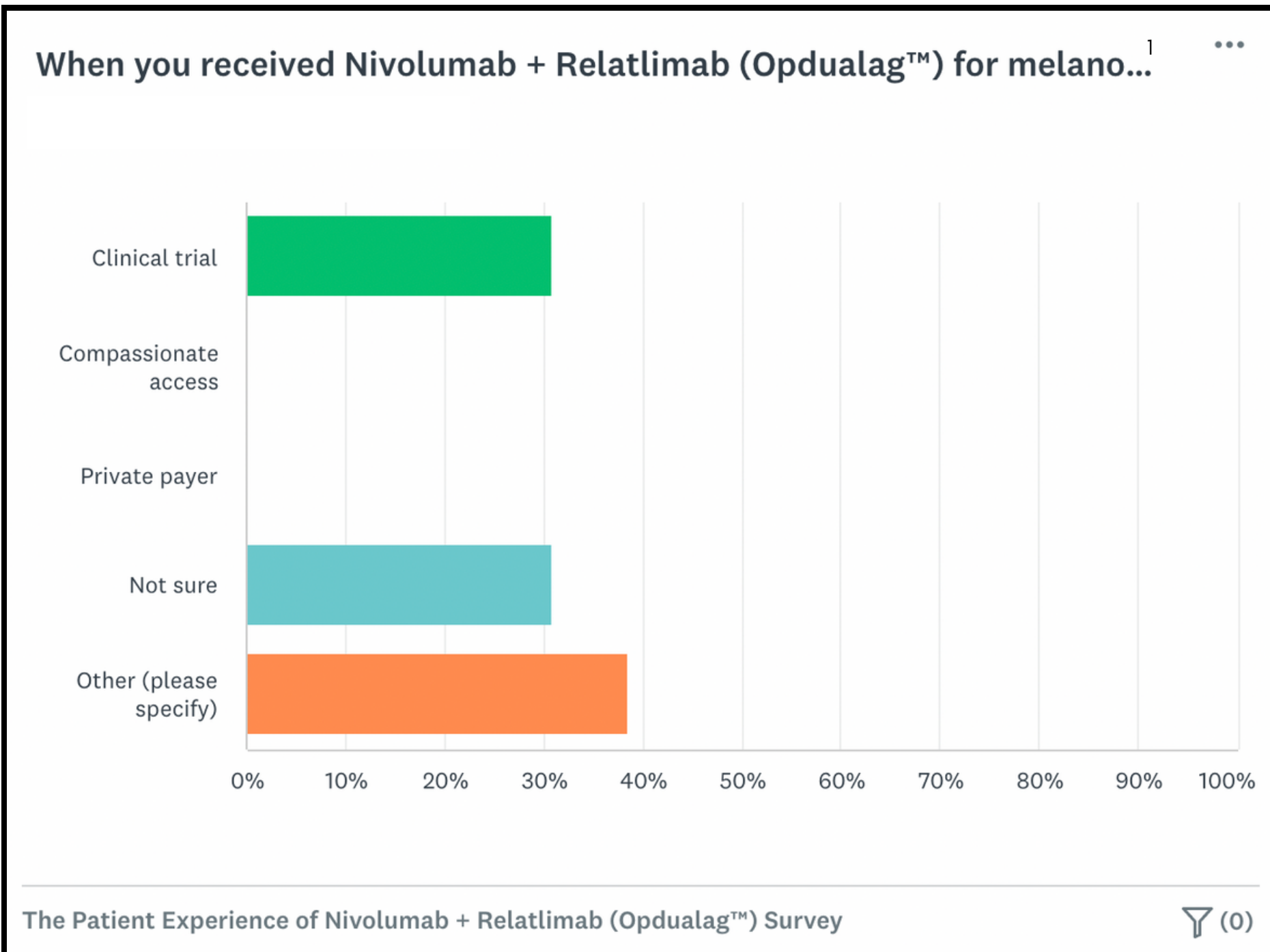


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Question 22: (1) Under what cancer stage and type context did you receive Nivolumab+ Relatlimab (Opdualag™) for melanoma?

French language participants have received Opdualag™ for stage IV and metastatic melanoma.

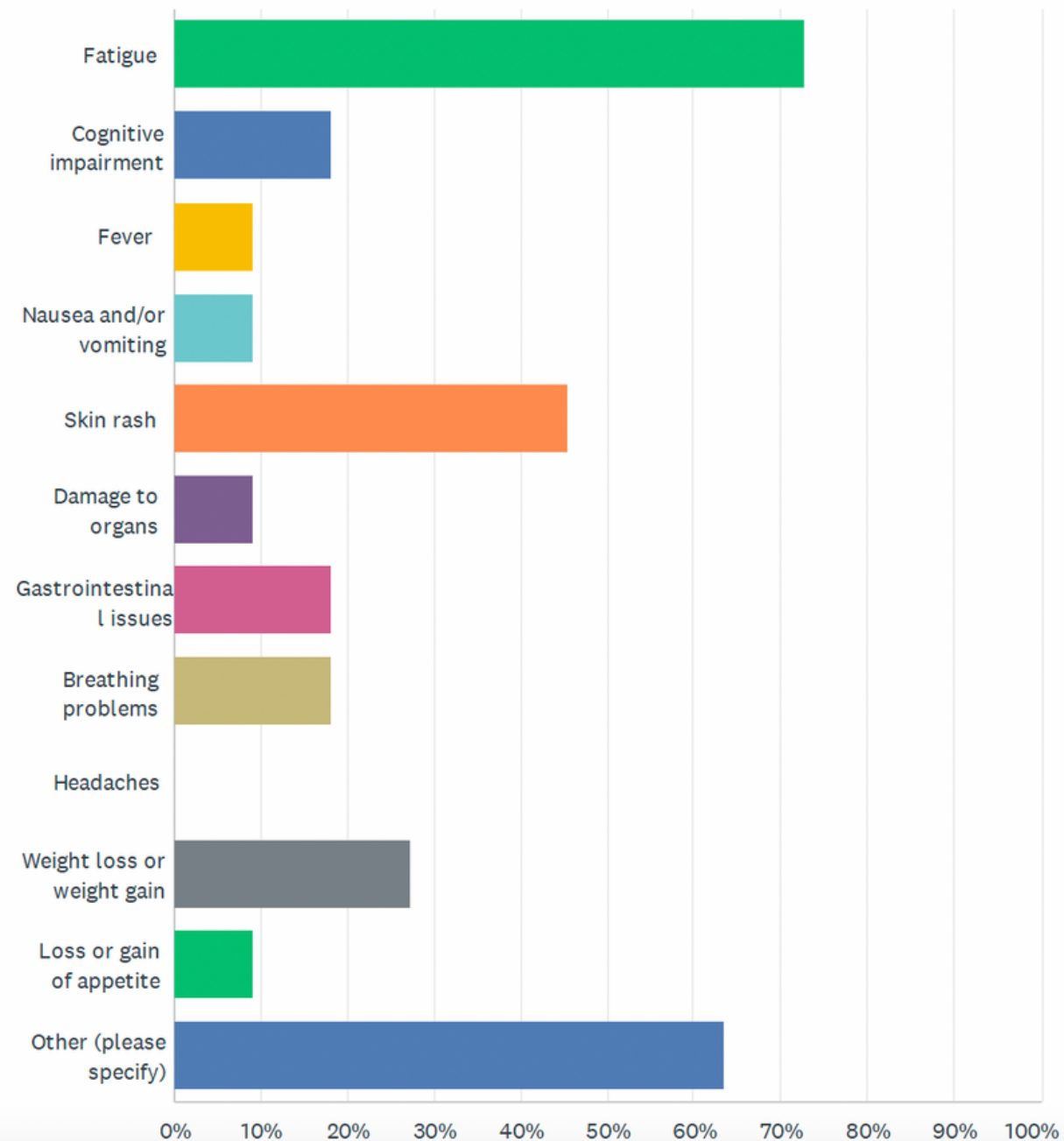


Question 23: (1) When you received Nivolumab + Relatlimab (Opdualag™) for melanoma, how did you obtain this treatment?

The French language participants did not offer a response to this question.

Written responses to this question indicated that medical centres frequently covered the cost for this care.

Q25 What (if any) side effects did you experience from this treatment?
Select all that apply.



Question 25: What (if any) side effects did you experience from this treatment [Opdualag™]?

The French language participants indicated that they experienced fever, headaches, and muscle aches.

Some of the comments added to the English language survey included adrenal insufficiency, kidney failure, and pneumonitis.

Question 26: Were these side effects manageable?



This question asked participants to rank the side effects they experiences on Opdualag™ on a scale from 1-5. 1 indicated that the side effects were not manageable; 2 that they were somewhat manageable; 3 that they were neutral or fell in the middle; 4 that they were mostly manageable; and 5 that they were completely manageable. The 3.1 average rating was the average of 8.33% voting that the side effects were not manageable, 41.67% voting that they were somewhat manageable, 16.67% that they were mostly manageable, and 25% for completely manageable. There was also a not applicable option, which was selected by 8.33% of participants.

The French language survey participants had a score of 2, with 100% voting that their side effects were somewhat manageable.

Question 28: (1) Did you experience any hardships that barred you from accessing this drug therapy? Was the treatment readily available to you? Hardships could mean having to travel long distances; not having quick access to treatment or having to personally pay the cost of therapy, for example.

Fortunately, the majority of the English and French language survey participants indicated that they did not experience hardships when accessing Opdualag™. Some participants did, however, list hardships which included:

- Travel times of at least one hour
- Financial burden of travel costs and time of work
- Having to personally pay for the treatment



Question 29: How important is/was it to you and your family members or caregivers that you received this treatment?

Across both the English and French language surveys, it was universally agreed that friends and family members of the participant found it important that they received Opdualag™.

“Saved my life, there is no question it was extremely important. Has allowed my 4 children and husband have me around for many more years than expected.”

“It was presented as a chance to give me hope for the future.”

Question 30: Are there any other aspects of your experience with this Nivolumab + Relatlimab (Opdualag™) you wish to note that have not been covered by the previous questions?

While most survey participants declined to answer this question after already being asked about Opdualag™ at length, a few participants added additional thoughts about their experience. These were evenly split between gratitude and noting the downsides of the experience, such as the high cost of the drug, severe side effects, and feeling isolated in their experience with immunotherapy.

"I do not believe I would be alive today were it not for this treatment. I spent the morning today with my 9 year old grandson. There's nothing better."

"I can't talk about Nivolumab without making reference to how difficult I found the treatments, due to the side effects. [...] The side effects can be overwhelming and can lead one to question whether it is worth doing."

"Because treatment is every 4 weeks I have been able to return to work part time which has been amazing to my sanity and our pocket book."



Concluding Questions: The Care Market and the Melanoma Experience

Questions 31–35

Question 31: If you could describe what you as a patient are looking for in new treatments coming to market, what would you say?

When asked what they would like to see in new treatments coming to market, participants from both the English and French language surveys prioritized:

- Fewer side effects (many)
- Longer response time (many)
- Having options in case of recurrence (several)
- Easier access to care (several)

Smaller numbers of participants cited: vaccine care options, more immunotherapy drugs in the market, TIL therapy, and less expensive care options.

Due to the overwhelming participant response to this question, the next slide will be dedicated to quotations from participants in response to question 31.

“Treatments with less side effects.”

“Something will less possibility of [adverse events]. I know now ipi-nivo can be really bad for most folks.”

“Opdualag for brain mets.”

“Treatments that are effective and provide long term survival with minimal recurrence.”

Every patient is different, there needs to be something for a greater audience.”

“I would like to see treatments that aren’t so brutal on the patients. The side effects can be overwhelming for some patients.”

“Concerned melanoma survivor looking for new treatments in case of recurrence.”

“Anything to help longevity.”

“Less toxicity, treatments that cure not defer recurrences, more rapid response.”

“I’d like to see treatments that would provide assurance of a longer survival rate, without metastasis.”

“I think treatment advancements are already pretty remarkable. I’d hope for everyone to have the easy time of it I had.”

Question 32: How might the quality of life of yourself and your caregivers change if a treatment available to you offered the improvements you describe in the previous question?

When asked what the changes suggested in the previous question would mean to their quality of life, participants from both the English and French language overwhelmingly expressed that their own quality of life, alongside that of their caregivers, would improve. In particular, participants mentioned:

- Less stress (many)
- Less side-effect related discomfort (several)
- Life extension (several)
- Less treatment time and being able to work (some)

“I would imagine I'd be able to live a more normal life. Not have to tell my kids no to playing soccer because I'll be in so much pain I won't be able to move the next day...”

“If the treatment could give me more time with less discomfort and compromise then our quality of life would be improved.”

“Less anguish. Improved outlook on survival.”

Question 33: What trade-offs did you (and your family/caregivers, if applicable) have to consider when selecting a therapy?

Across the English and French language surveys, participants cited the following as the trade-offs they (and their caregivers) had to consider when making their treatment plan:

- Many participants suggested that they did not consider there to be many choices to be made, as they were going to do what they had to in order to survive
- Questioning whether the side effects and TRAEs are worth it (several)
- Financial considerations (some)
- Some did not feel they were part of the decision
- Smaller numbers of participants mentioned transportation, having to leave their families/communities repeatedly, and what would be easiest on their caregivers

“Leaving our community and travelling across the country repeatedly. Not being available to our kids and grandkids and my elderly mom.”

“Give up life as we know it to try and stay alive.”

“Certain choices preclude any followup options.”

“Taking an easier job that didn’t require as much cognitive alertness; also the cost of targeted treatments [...] means you’re an insurance risk and thus jobs are at risk. Recruiters don’t touch you. So you’re caught having to take whatever you can.”

Question 34: Please briefly describe the impacts melanoma has had on your daily life.

Question 34 asked participants to describe the effect melanoma has had on their daily lives. Across both the English and French language surveys, participants indicated:

Lasting physical side effects (many)

Anxiety (many)

Fear of the sun (several)

Fear of death (several)

Daily preoccupation (some)

Constant pain (some)

Loss of career (some)

Loss of sense of taste (some)

Sleeping poorly (some)

Sun safety advocate (a few)

Bedridden (a few)

New appreciation of life (a few)

Fears about future (a few)

"If I do not get enough sleep at night, I wake up sick and then the whole day is a struggle. Just doing everyday task become[s] impossible."

"I am now quite terrified of the sun!! I use 60 sun block most days, and bought two large-brimmed hats. On days with high heat, I don't go out."

"Children and all of the family having anxiety every time changes happened. Mental anxiety lead to my husband having to take time off work and change jobs. Leaving the work force for many years causing me to give up my dental Hygiene licence. All in all a life changing experience for everyone."

"I still enjoy walks with friends and a good life with my partner. I miss being able to taste food and I miss my home and family while away getting treatment."

Question 35: Are there any aspects of melanoma that you feel are more important for you to control than others, to maintain your quality of life?

Across the English and French language surveys, participants listed the following as aspects of melanoma they feel it is the most important to control:

Sun exposure (several)

Tumour growth/recurrence (several)

Follow up appointments (several)

Skin checks (several)

Updated disease knowledge (a few)

Pain management (a few)

Healthy diet (a few)

Addressing fatigue (a few)

Ongoing side effects (a few)

Positive attitude (a few)

Staying active (a few)

Psychological support (a few)

Sleeping well (a few)

“I research my scan reports and push for what I feel needs to be done. And my pain. If my pain wasn't managed with the steroid (for now) I wouldn't be functional at all.”

“The effects of melanoma and the side effects of treatments cause a loss of vital energy, making all aspects of life more challenging. The most important thing to control and maintain is a positive attitude.”

“Yes, knowing the latest research to advocate for best course of treatment, increased prevention strategies to keep reoccurrence at bay.”

Key Takeaways

- Only approximately one quarter of survey participants received companion diagnostics testing (24.56% across both surveys)
- Only 54.55% of English language survey participants completely understood why they were receiving companion diagnostics testing; 36.36% indicated that they did not understand why or it was not explained to them
- The majority of survey participants who received Opdualag™ did so in the stage IV setting (75%) with metastatic melanoma (75%). A large number of participants also had unresectable melanoma (33.33%).
- The most frequently cited side effect of Opdualag™ was fatigue (66.66%) followed by skin rashes (41.66%)
- Opdualag™ is seen by participants as having a reasonably manageable side effect profile, with English language participants rating it 3.1/5, with 5 indicating completely manageable side effects
- When asked what they are looking for in future care options, participants overwhelmingly responded that they are looking for treatments with easier side effect profiles, greater potential for longevity, and the ability to have options in case of recurrence
- The most frequently cited “trade-off” participants considered when making care decisions was whether the side effect profile of a treatment was worth it

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