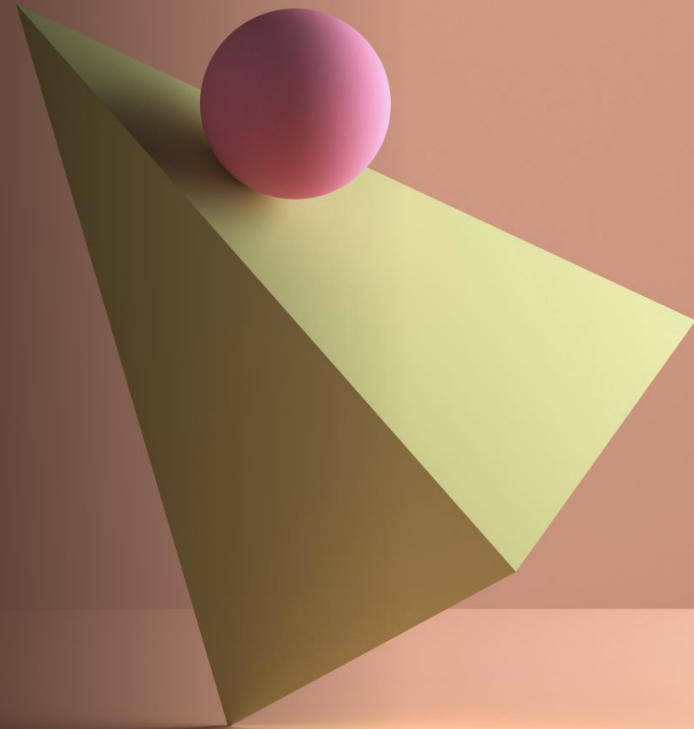




US Manufacturing Waiver Survey

May 2023



Summary

Today there is a renewed interest in the domestic manufacturing waiver process under the Bayh-Dole Act, yet there is little data on the use of those waivers. In order to gather metrics on the use and impacts of waivers, AUTM created a survey in Spring 2023 to inform its stakeholders.

Findings

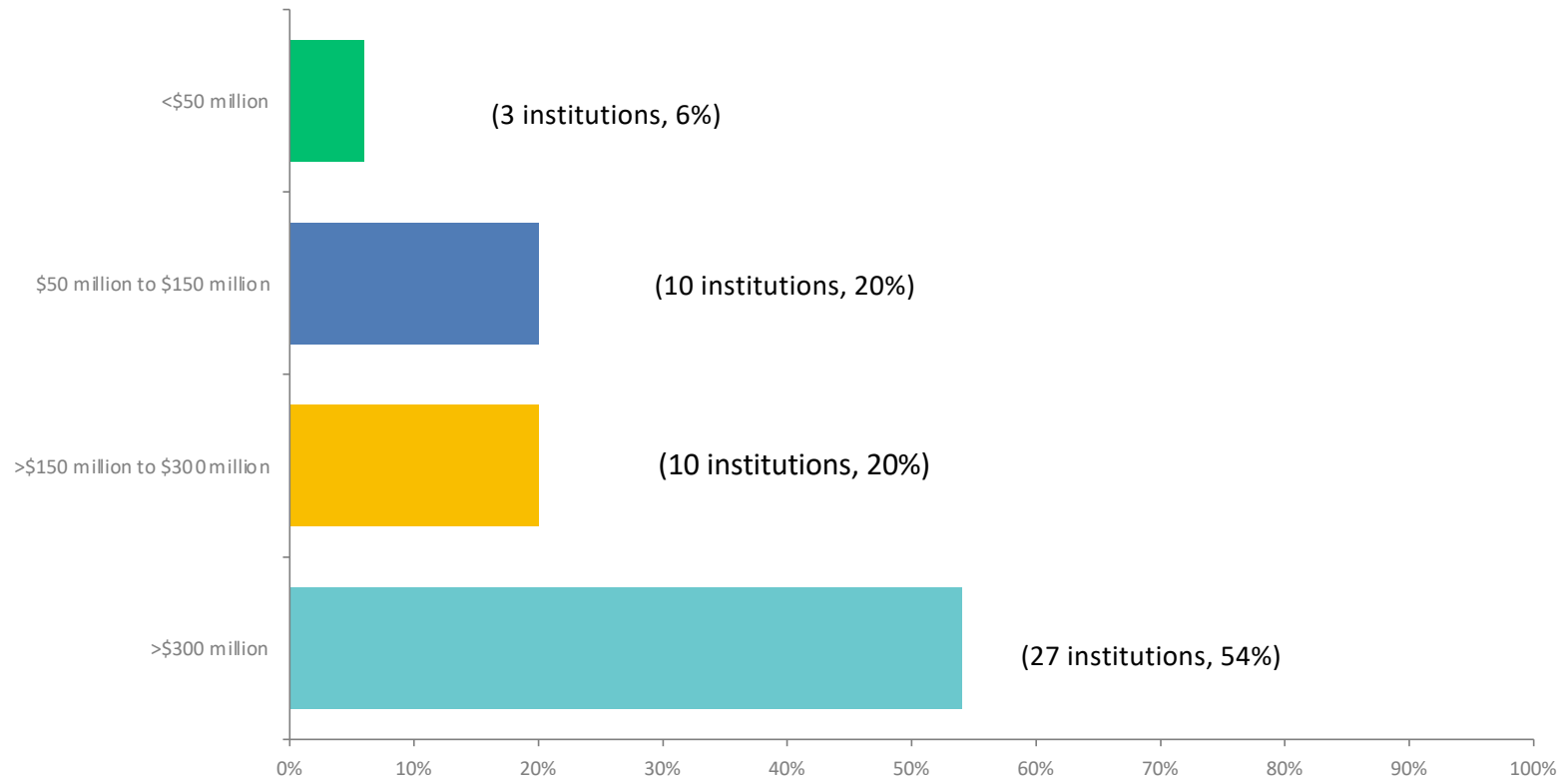
Data was collected from 51 technology transfer offices. The results follow:

- 27 respondents (54%) reported research expenditures above \$300 million.
- 2 respondents (4%) reported filing one waiver in the past year.
- 13 respondents (25%) reported filing at least one waiver in the past 5 years.
 - 22 waivers were filed in total by those institutions.
- 5 respondents reported that all or some of their waivers had been granted.
- 33 institutions responded to the question about the average time it took to hear back from the funding agency regarding their waiver request:
 - 22 respondents reported that they never received a response,
 - 8 respondents said it took more than a year to receive a response, and
 - 3 respondents reported that it took less than a year to receive a response.

*Not all institutions responded to every question.

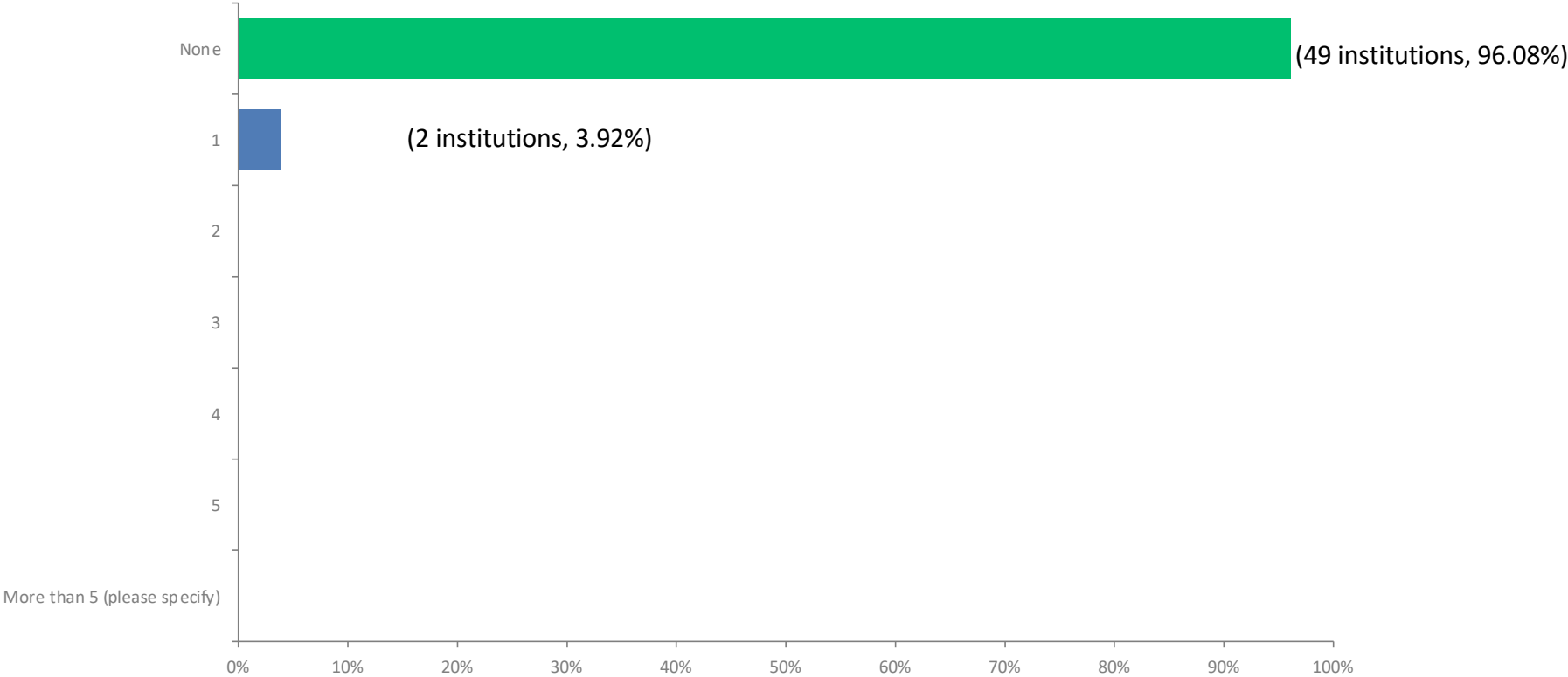
How large is your institution in terms of research expenditures?

Answered: 50 Skipped: 1



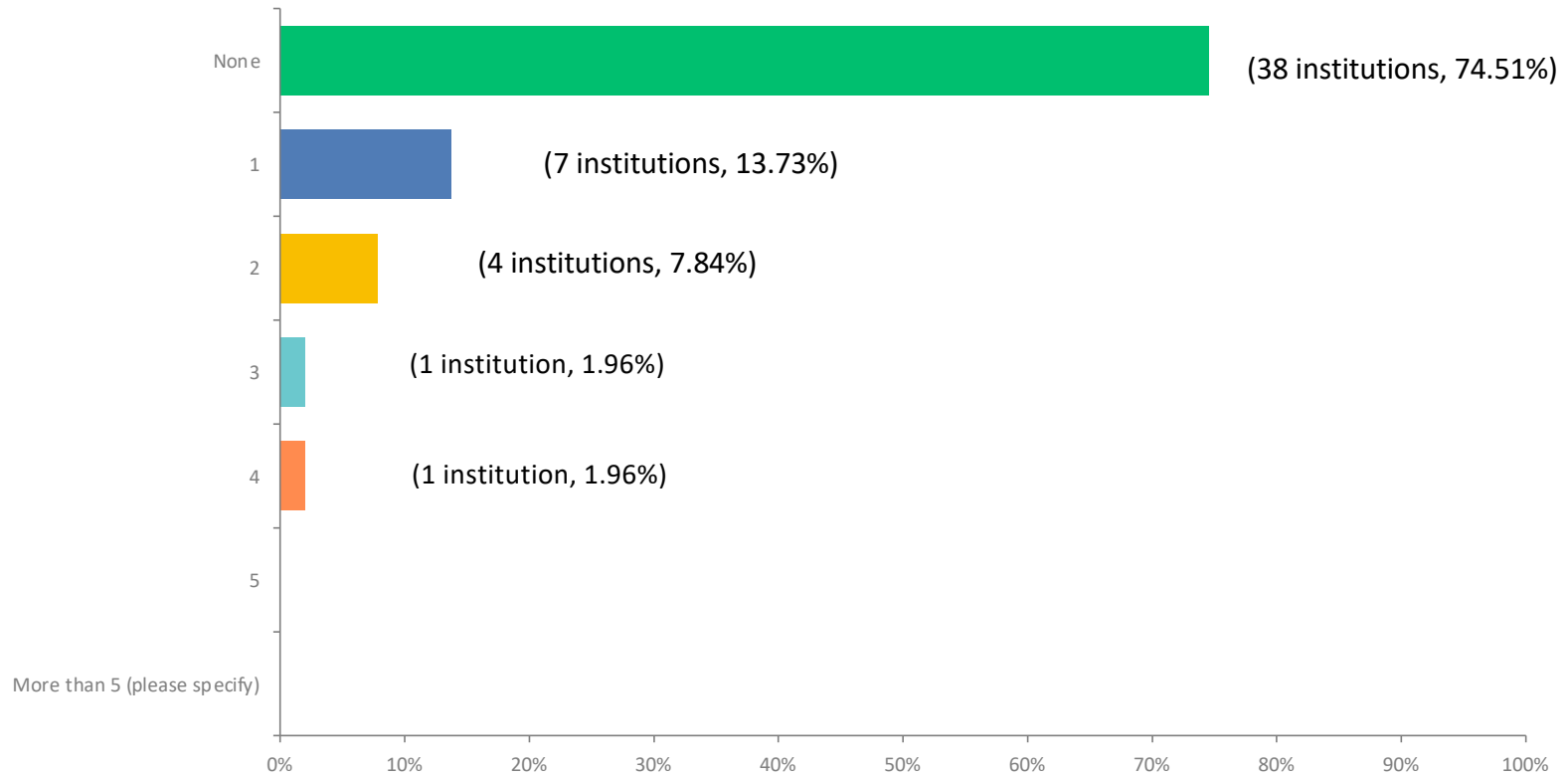
In the past year, how many waivers has your office filed?

Answered: 51 Skipped: 0



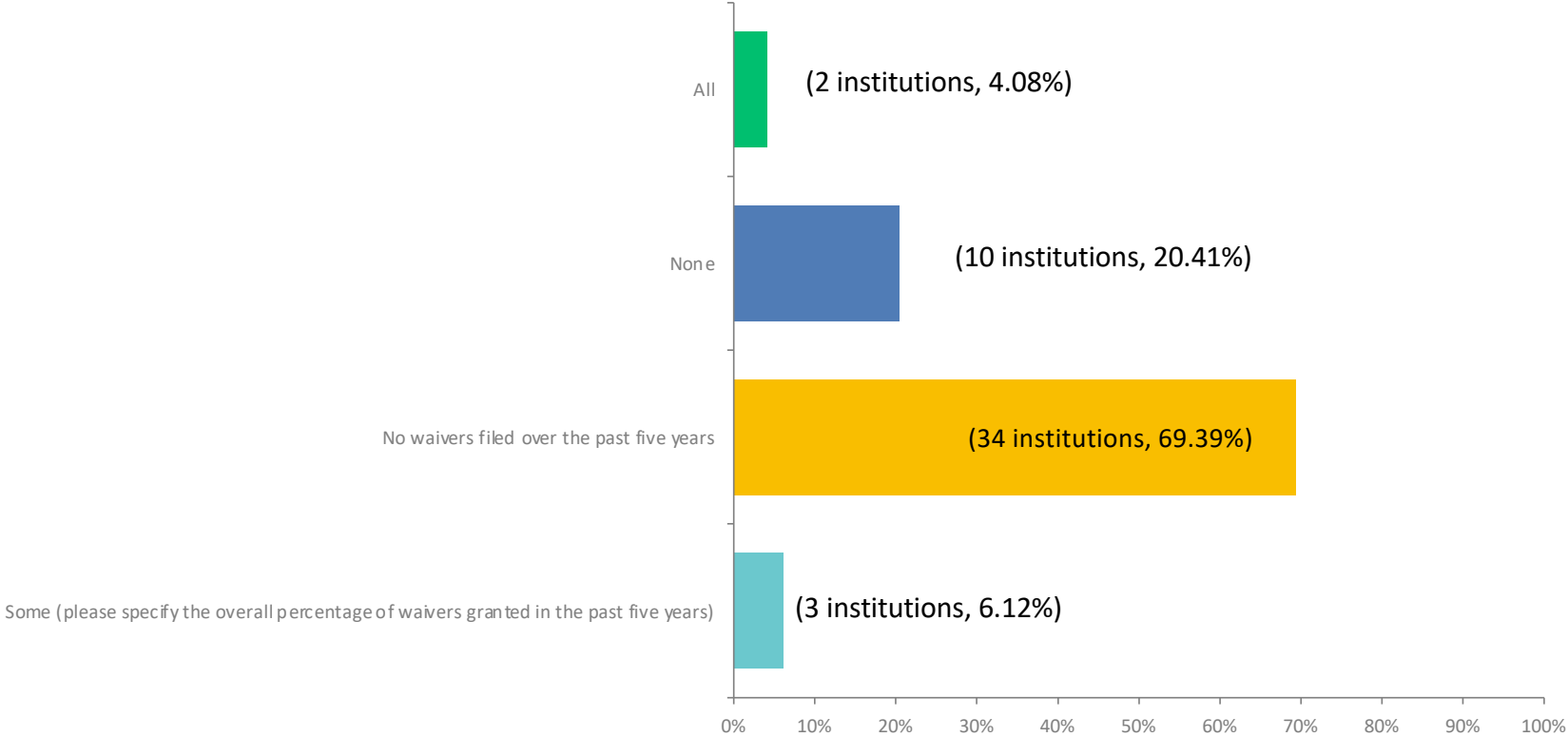
How many were filed in the past 5 years?

Answered: 51 Skipped: 0



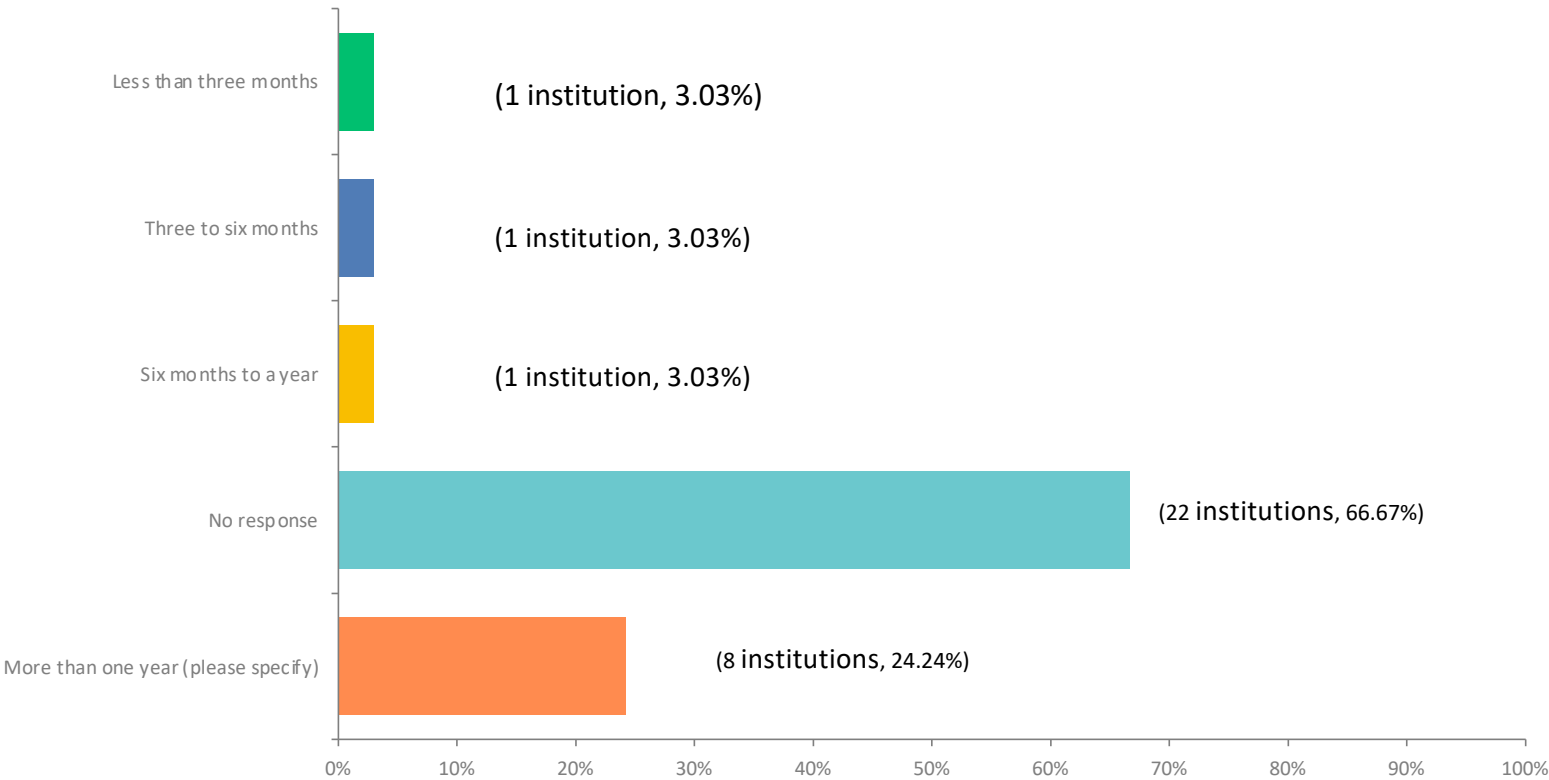
How many of your waivers over the past five years were granted?

Answered: 49 Skipped: 2



On average, how long did it take to receive a waiver request response from the funding agency?

Answered: 33 Skipped: 18



Survey Comments

“The waiver process is completely busted. Not only did we spend precious non-profit research dollars on requesting legal help in navigating the waiver process it was useless. The end result is that because the company could not get a US waiver, the availability of the product for US patients was blocked. The product is available globally except in the US because of this issue. So, US patients are suffering.”

“Overall, experiences were manageable, yet frustrating and could have been more streamlined. Each agency has their own process. It would be beneficial and more productive to have consistency across the board, as there is a lot of recreating the wheel when submitting a request for U.S. manufacturing waiver. Time is another concern.”

“We have had prospective licensees who avoided licensing or substantially changed the terms of a license agreement because of their concern for the length of time it would take/uncertainty of getting a waiver.”

About AUTM

AUTM is the non-profit leader in efforts to educate, promote and inspire professionals to support the development of academic research that changes the world and drives innovation forward. Our community is comprised of about 3,000 members who work in more than 800 universities, research centers, hospitals, businesses and government organizations around the globe.

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