

# IDENTIFYING THE GAP: IGEN TEAMS AND REGULATORY UNDERSTANDING

2024



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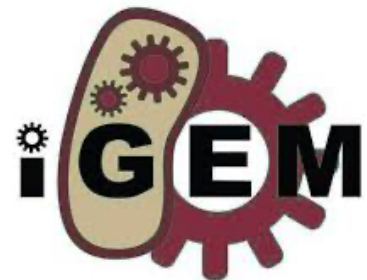
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# INTRODUCTION

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QGEM (Queen's University) and Cornell iGEM (Cornell University) came together to collect data from iGEM participants on their current knowledge of their countries unique regulatory policies. We sent out a survey: <https://forms.gle/GFtQn1XeQf728ATt6> to various iGEM teams worldwide in hopes of finding a gap in knowledge in regulatory understandings. This booklet details the results of our survey and a brief analysis. Future directions from the results are also detailed in our conclusion.

iGEM participants are tasked with using synthetic biology to tackle current real world problems. This leaves a lot of responsibility in the hands of these creators. It is important to have knowledge on regulatory practices. Regulations are more than just a checklist of administration tasks, they are an essential part of maintaining responsible scientific advancement. Many iGEMer's are not aware of many of the regulatory practices in their country. They are not to blame for this as for many of us this is not common knowledge. Nonetheless this gap in knowledge can lead to unintentional consequences and mistakes.

The data we have analyzed includes responses from the following home countries of participants and their respective team:

- Countries: Australia, Canada, USA, China, Mexico
- Teams: QGEM, Cornell iGEM, FSU iGEM, iGEM TUM Campus Straubing, USyd iGEM

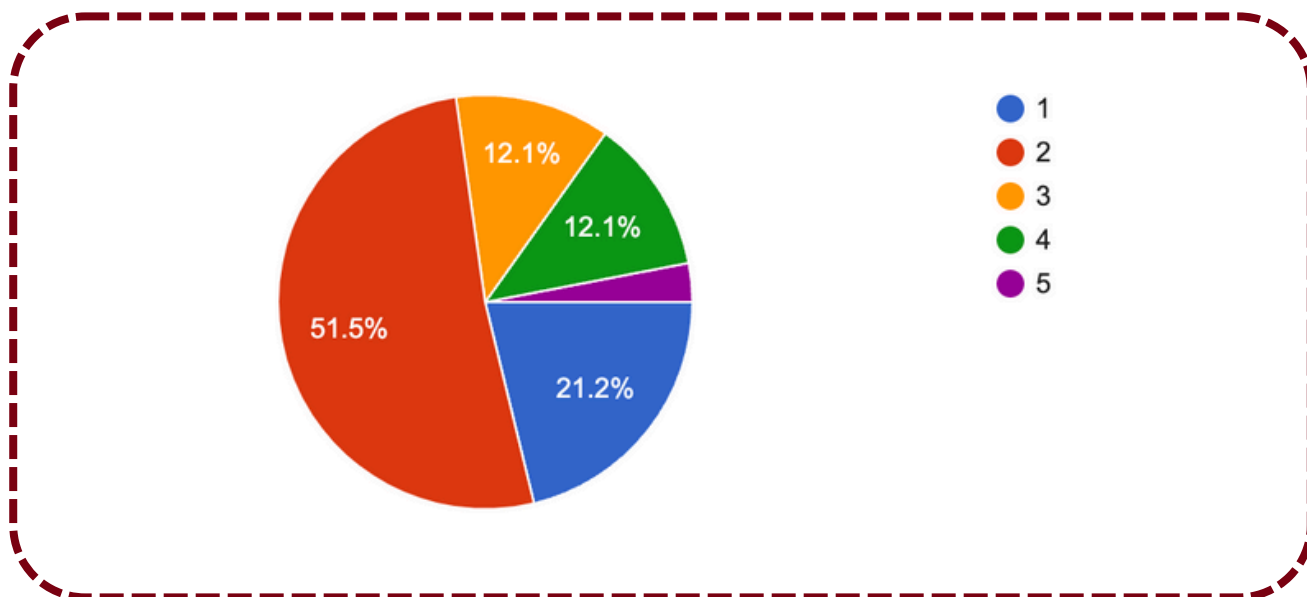
We divided the teams into 4 categories for further analysis:

1. Human Health (Food and Nutrition, Diagnostics, Therapeutics, Oncology, Infectious Disease)
2. Environmental Impact (Agriculture, Climate Crisis, Bioremediation, Conservation)
3. Software and Hardware Manufacturing (Biomanufacturing, Foundational Advance, Software and AI)
4. Societal Impact (Fashion & Cosmetics, Space)

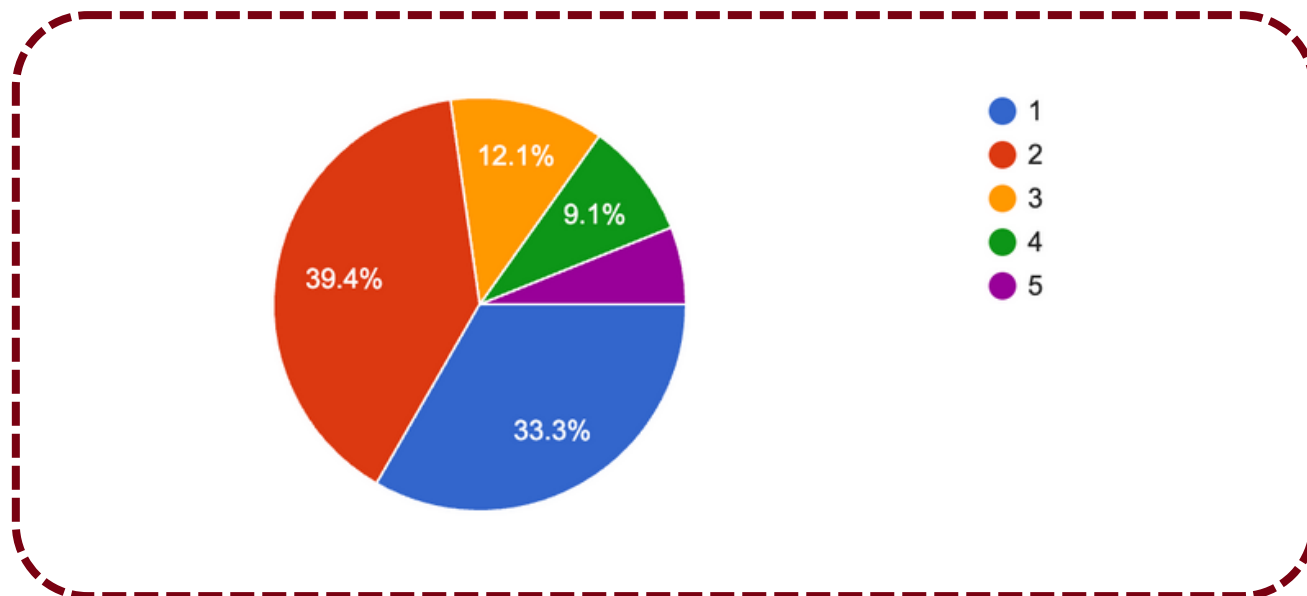
We used a 1-5 ranking scale for knowledge. A 1 indicated little knowledge and a 5 indicated extensive knowledge.

With this booklet we aim to identify any gaps in knowledge in the regulatory world and pave the way for future teams to expand on our findings. We hope to foster positive collaboration and awareness. Together we can enhance regulatory compliance in the iGEM world and work together to better society!

# BASIC KNOWLEDGE

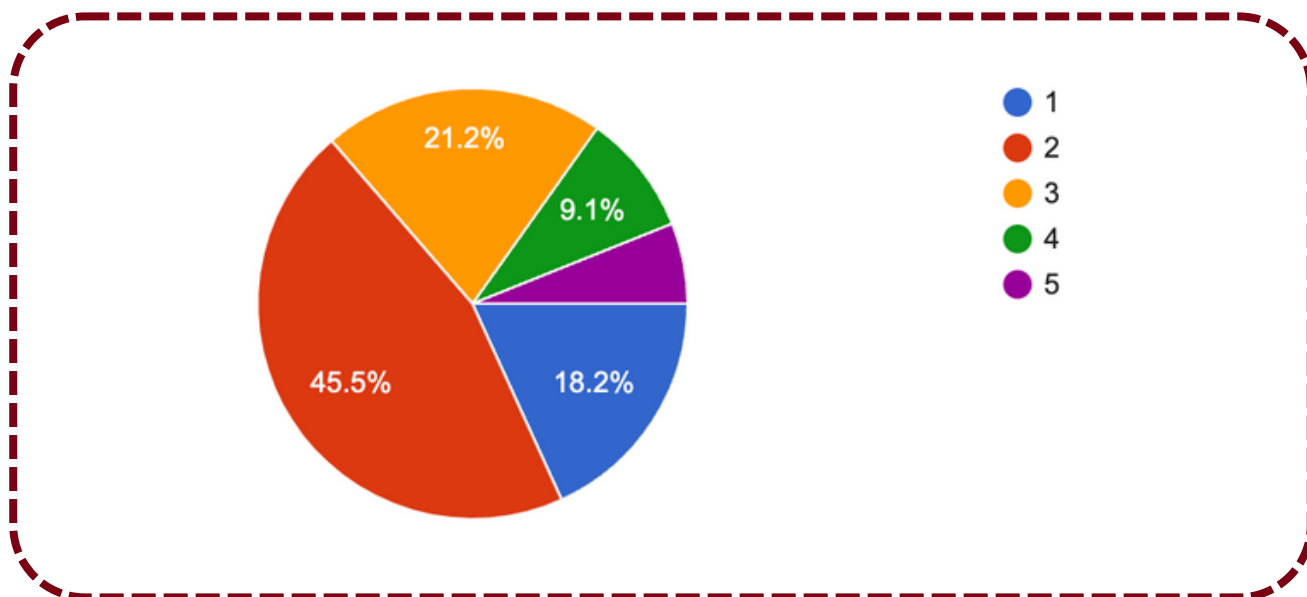


**Figure 1.** 84.8% of iGEMer's ranked themselves at a 3 or lower for their knowledge about their countries' biosecurity policies.

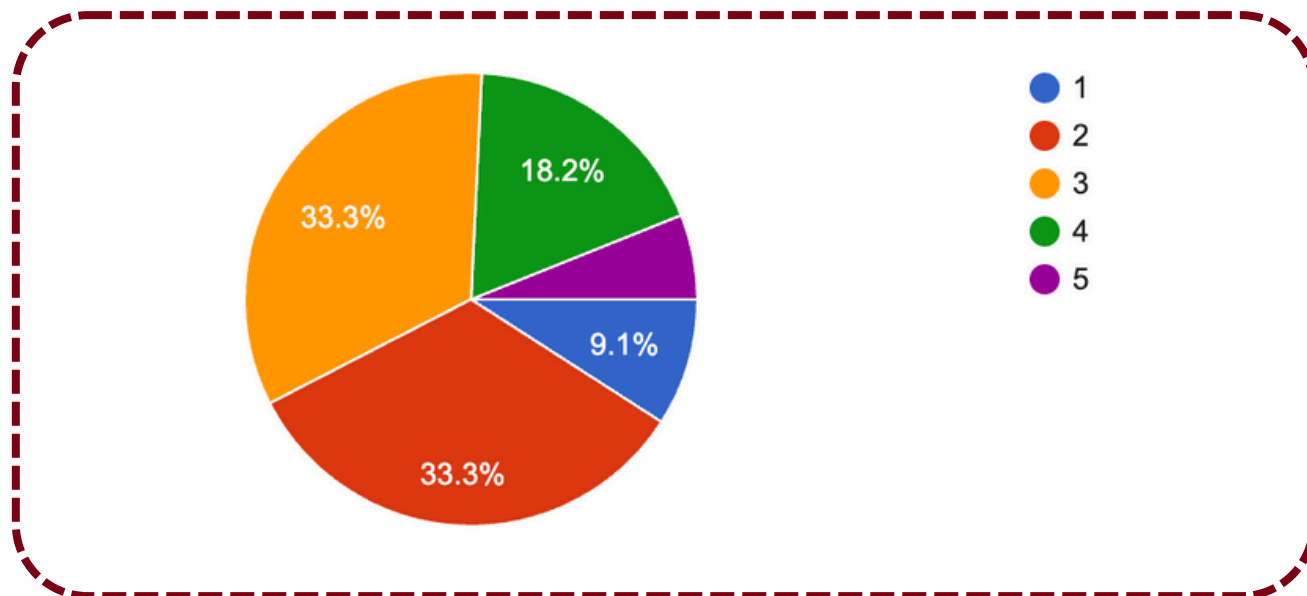


**Figure 2.** 84.8% of iGEMer's ranked themselves at a 3 or lower for their knowledge about their countries' manufacturing policies.

# BASIC KNOWLEDGE

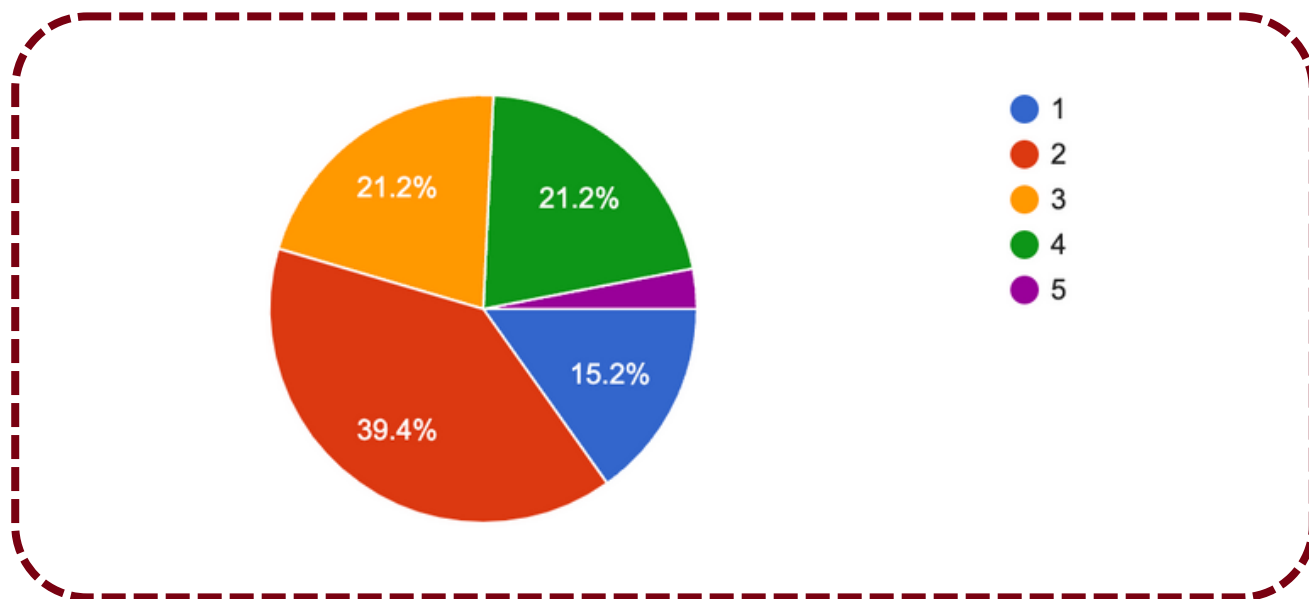


**Figure 3.** 84.9% of iGEMer's ranked themselves at a 3 or lower for their knowledge about their countries' general regulatory documents.

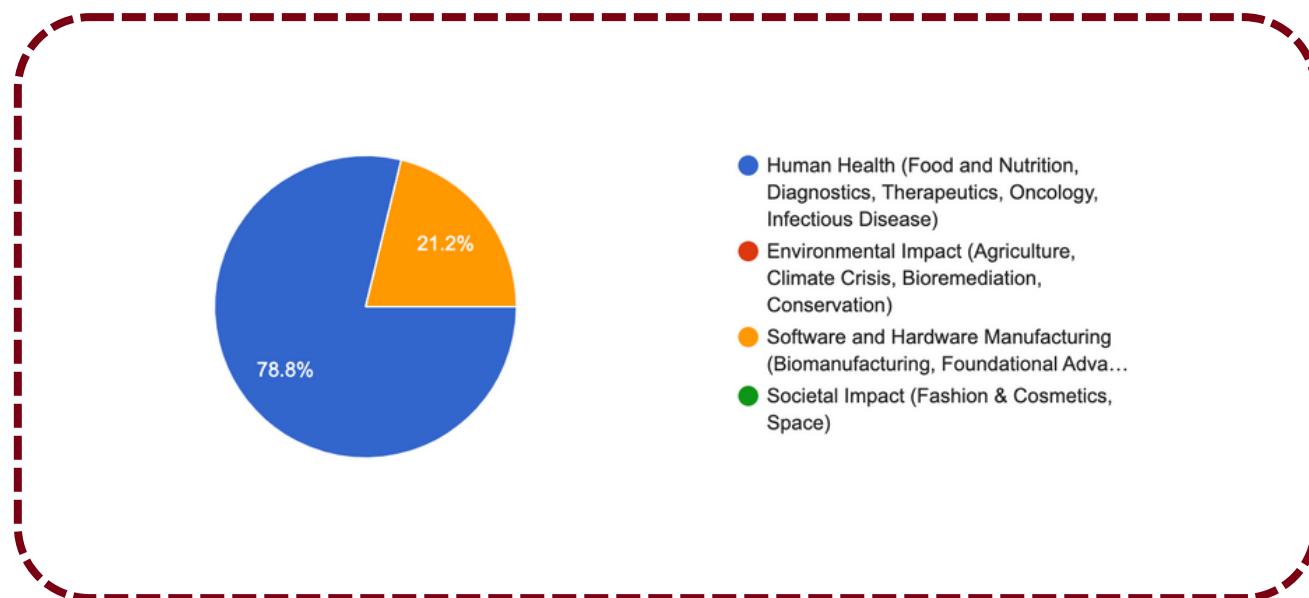


**Figure 4.** 75.7% of iGEMer's ranked themselves at a 3 or lower for their knowledge about their countries' ethical committees and their responsibilities.

# BASIC KNOWLEDGE

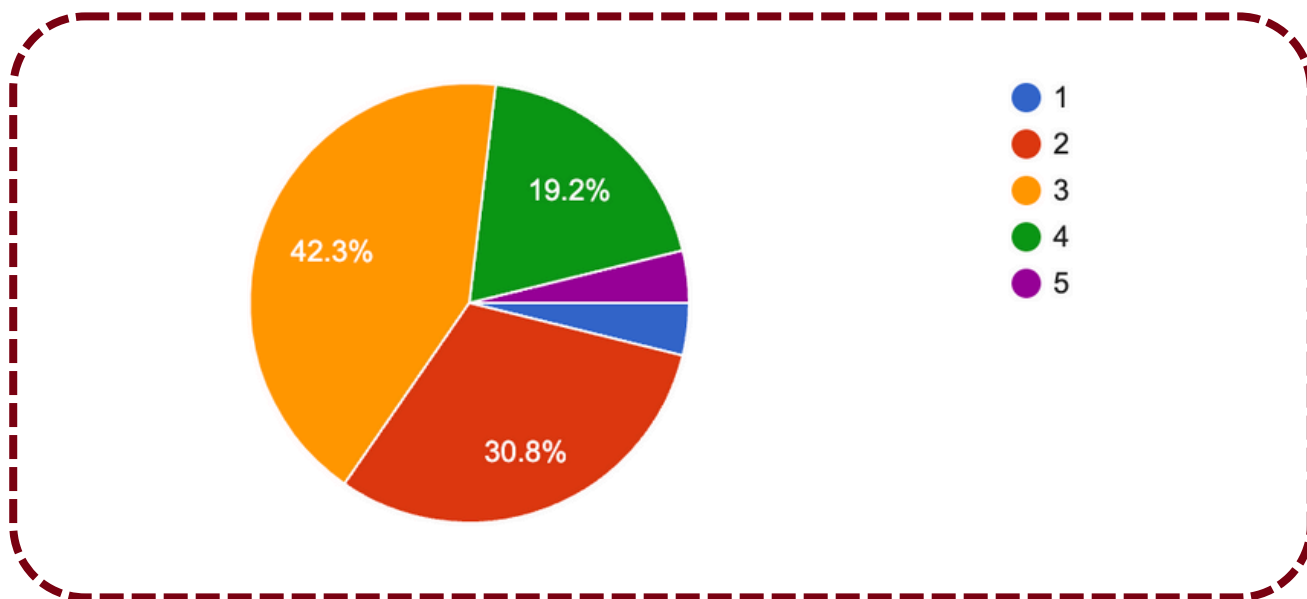


**Figure 5.** 75.8% of iGEMer's ranked themselves at a 3 or lower for their knowledge about their countries' research and design regulations.

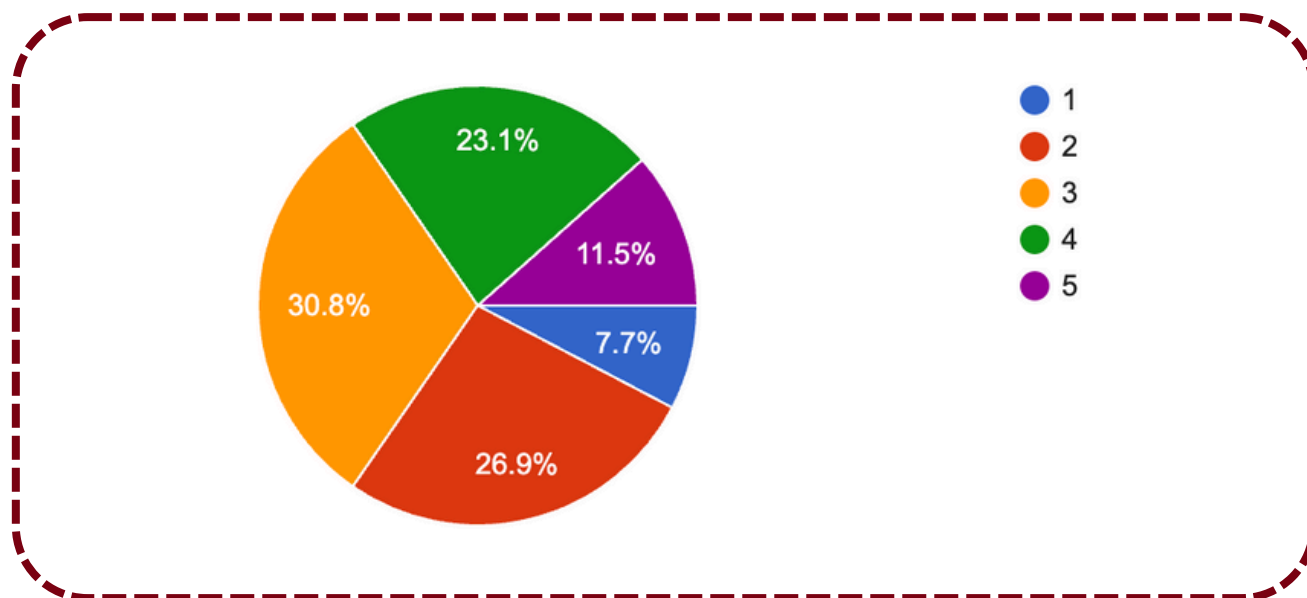


**Figure 6.** 78.8% of iGEMer's projects out of 33 responses were in food & nutrition, diagnostics, therapeutics, oncology or infectious disease.

# HUMAN HEALTH



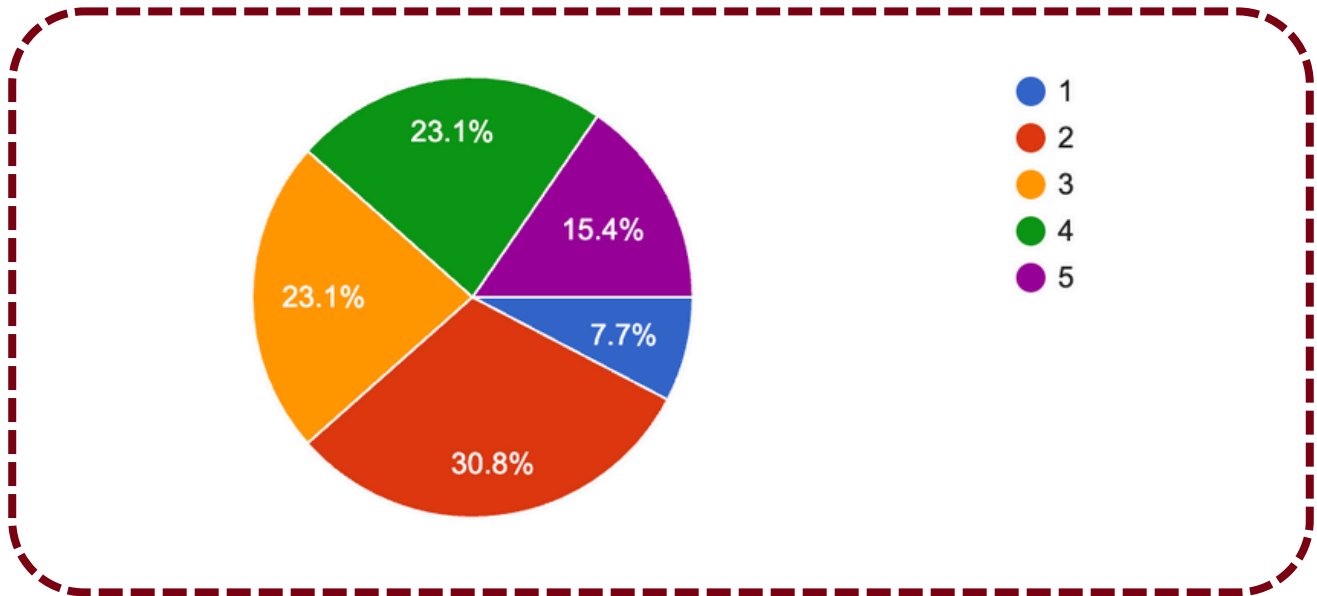
**Figure 7.** 76.9% of iGEMer's ranked themselves at a 3 or lower for their knowledge about their countries' food and drug regulations.



**Figure 8.** 65.4% of iGEMer's ranked themselves at a 3 or lower for their knowledge about their countries' clinical trial regulations.

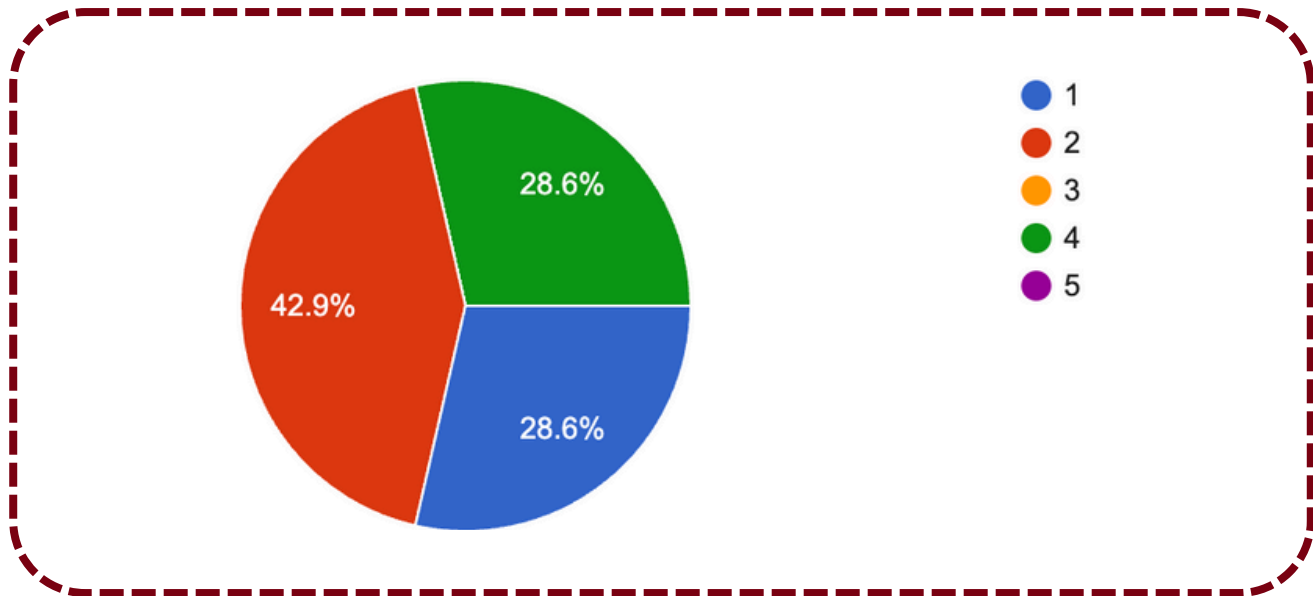
# HUMAN HEALTH

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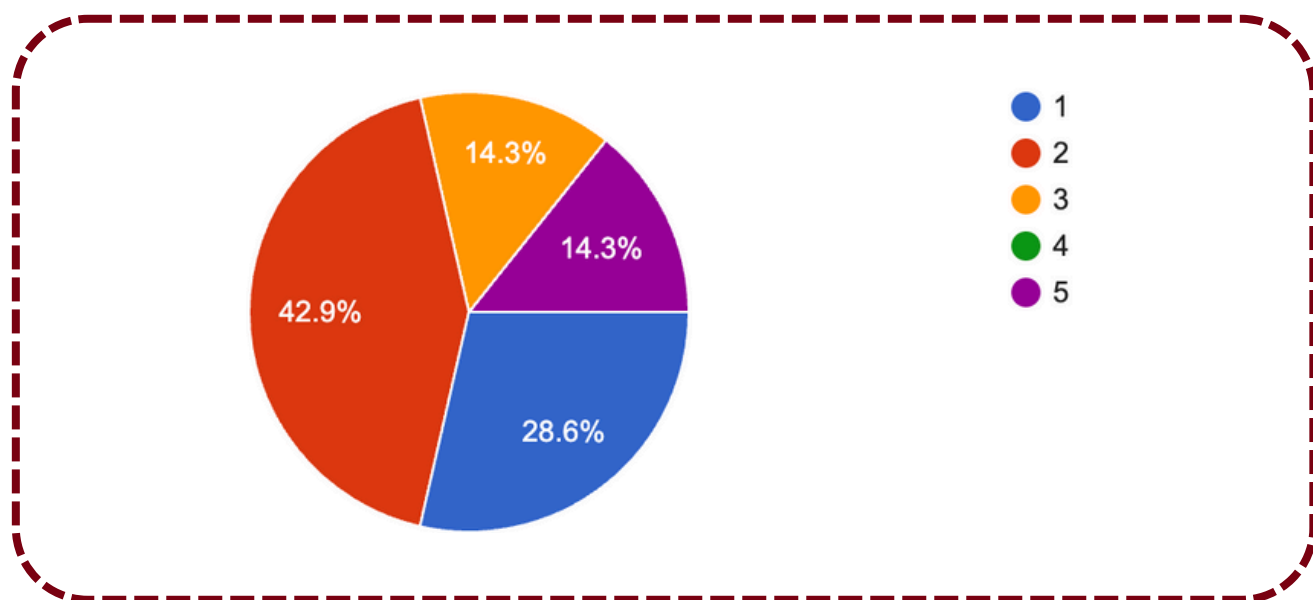


**Figure 9.** 61.6% of iGEMer's ranked themselves at a 3 or lower for their knowledge about their countries' informed consent policies.

# SOFTWARE/HARDWARE MANUFACTURING



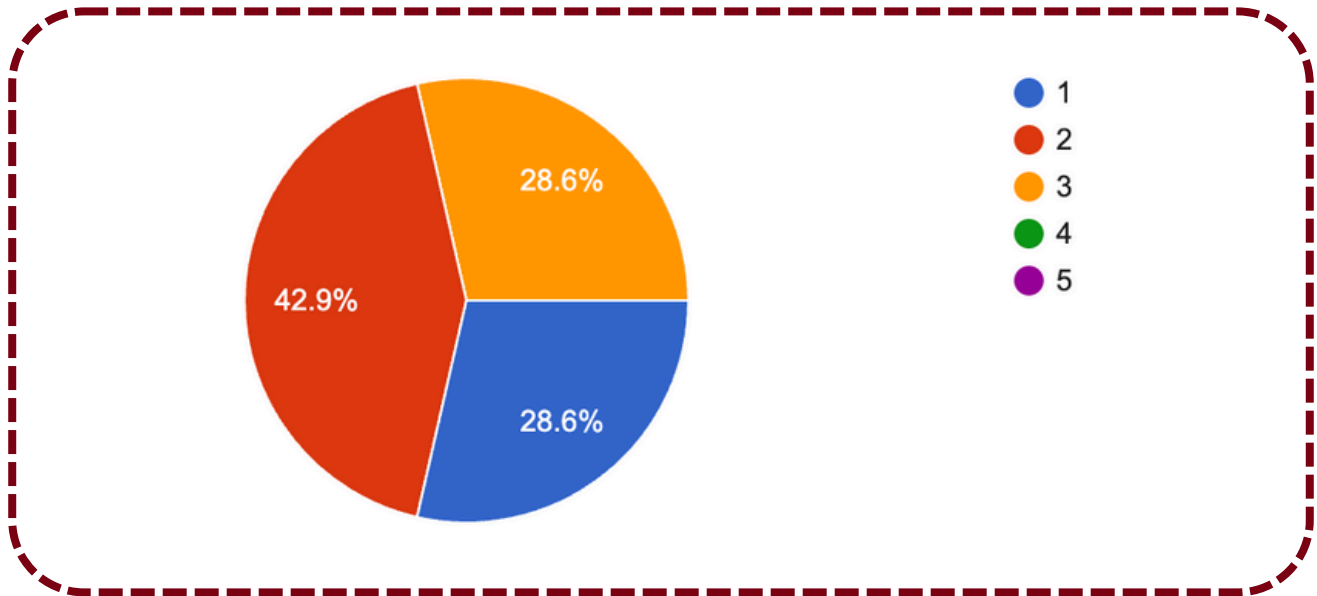
**Figure 10.** 71.5% of iGEMer's ranked themselves at a 3 or lower for their knowledge about their countries' manufacturing regulations



**Figure 11.** 84.8% of iGEMer's ranked themselves at a 3 or lower for their knowledge about their countries' manufacturing policy department

# HUMAN HEALTH

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**Figure 12.** 100.0% of iGEMer's ranked themselves at a 3 or lower for their knowledge about their countries' assurance of a safe, fair and consistent market for all people.

# CONCLUSION

In conducting this survey of iGEM teams around the world, we have learned much about the way different teams perceive regulations and policies based on their respective project. In terms of human health (Food and Nutrition, Diagnostics, Therapeutics, Oncology, Infectious Disease), we saw that a significant number of team members ranked themselves a 3 or lower in terms of understanding various regulations or policies that might inform their project, including food and drug regulations, clinical trials and informed consent.

We saw a similar trend occur in the Software, Hardware and Manufacturing category (Biomufacturing, Foundational Advance, Software and AI) where near 70% of all members surveyed did know their countries' manufacturing policy, and a staggering 100% of members who took this survey did not know their countries' assurance of a fair market.

It is notable that we unfortunately did not yield enough data from the categories of Environmental Impact (Agriculture, Climate Crisis, Bioremediation, Conservation) and Societal Impact (Fashion & Cosmetics, Space) to generate a graph, and as such these teams are excluded from the data. However, given the trend of 60-70% of iGEM members ranking a 3 or below for all questions, it might be reasonable to assume a similar trend. However, of course, it is necessary to get more data from teams in these categories.

In total, these results clearly indicated that there is a gap in knowledge among iGEM teams from around the world regarding their country specific regulatory policies. Regulatory policy is a guiding corner stone of research, no matter the field. It is how we as iGEM members and the greater research community practice safe, ethical inclusive practices throughout our work.

Given that regulatory policies might widely vary from country to country, we propose the creation of a regulatory handbook that compiles regulatory guidelines from different countries across the globe. This regulatory handbook could serve as reference framework for future iGEM teams to look to for guidance on the local regulations and policies that might impact their project. We hope that through the creation of this handbook, we might be able to create a deeper understanding of the different regulatory practices that would impact our work not only as iGEM members, but as researchers who aim to better the world.