# The Process of Cancer Research and Development

This activity was created by Gustavus students to aid high school students and conference attendees in their understanding of how cancer research occurs and the challenges that researchers may face while developing treatments.



### 1. Research Discoveries

You are a scientist at Gustavio Adolphonzo Pharmaceutical, where your role is to develop a new treatment for LMNOP cancer. After inserting the C-Nobelia gene into some cells, you notice the presence of a protein that increases tumor resistance. From this discovery, you have collected data that you hope to use in a grant proposal that you will write to garner funding for your project.



To determine if your data is feasible, draw one marble from the opaque beaker in front of you...

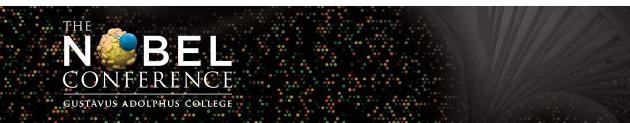
If the marble is green: Your data analysis went well and your methods worked smoothly! Note that most research projects take place over the course of many years, and luckily, yours was successful. Place the marble in the clear beaker and move to the GRANTS AND FUNDING table.

If the marble is blue: There was a problem with your instrumental analysis and you need to troubleshoot your methods. During research, a great deal of time is spent optimizing methods to create a better understanding of the data obtained and what it reveals about the biological processes being studied. Place the marble in the **clear beaker** and pick another marble out of the opaque beaker.



### 2. Grants and Funding

Congratulations on your recent discovery! Now that you have a potential cancer treatment, your lab needs to receive funding to continue understanding the pathway that this treatment uses to combat cancerous tumor cells. In order to obtain the necessary funds, you must write and submit your grant proposal to an outside funder such as the National Cancer Institute.



To determine if your project receives adequate funding, roll the die on the table...

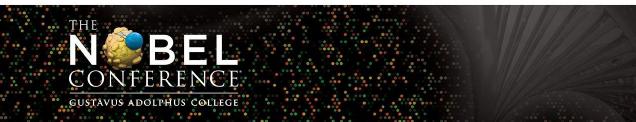
**If you rolled an even number:** You were able to garner the right amount of funding for further exploration of your project. In 2018, the National Cancer Institute funded 4,780 Research Project Grants. Leave the die on the table and move to the CANCER TREATMENT DEVELOPMENT table.

If you rolled an odd number: The odds are against you. You were unable to obtain the funds needed to carry out further research. Note that the National Cancer Institute only allocates 41.3% of its total budget to fund its Research Project Grants. Rewrite and resubmit your proposal by rolling the die again.



### 3. Development

Now that you have received funding, know that the focus of your research has to align with what you proposed in your grant. You have a well developed plan from your proposal, but there is a lot of work still left to do.



To determine how the development of your project unfolds, choose one card from the deck and check its suit...

**If it is hearts**: Miraculously, you are able to obtain all of the data and analysis necessary for your project. Move to the FDA APPROVAL/CLINICAL TRIALS table to begin the process of getting your treatment approved by the FDA.

If it is clubs: Unfortunately, you run out of funding before obtaining conclusive results. The strain of cells that your project relies on are incredibly expensive, and due to contamination from misuse, your supply is unusable. Move back to the GRANTS AND FUNDING table to garner more funding for the continuation of your project.

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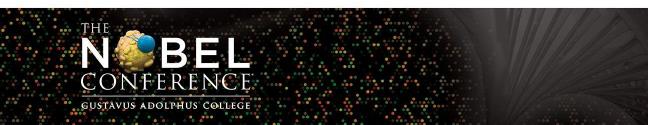
**If it is spades**: After insertion into another mammalian system, there was an error during protein synthesis. The protein associated with C-Nobelia gene was misfolded into a detrimental protein. Draw a new card and check the suit to further investigate this issue.

If it is diamonds: Your instrumentation malfunctions, delivering a hiccup to your data accumulation. Since you have to wait several months for the shipment containing a piece of equipment to arrive, draw a new card and check the suit.



### 4. FDA Approval/Clinical Trials

Finally, your dedication to the C-Nobelia protein has brought forth a possible cancer treatment that is ready to begin the process of approval. First, you must submit an Investigational New Drug (IND) application to the FDA. If the application is approved, clinical trial phases I-III can begin. If phases I-III do not bring forth any concerns, you must submit a New Drug Application (NDA) to have your treatment approved for the market.

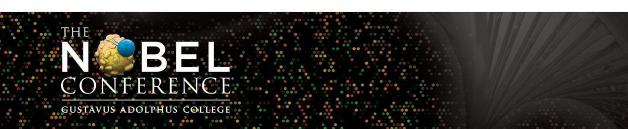


To determine whether your cancer treatment is cleared for clinical trials, and whether the FDA approves its use for the general public, spin the wheel...

**If you land on green/yellow:** Your IND application was approved and no issues arose during clinical trial phases I-III. Therefore the FDA approves your NDA and clears the treatment for production and public use. Move to the APPROVED TREATMENTS AND MARKETPLACE ISSUES table.

**If you land on blue/purple:** Your IND application was approved, but during clinical trial phase III, your cancer treatment was found to cause undesirable long-term side effects. In turn, you do not submit an NDA, but instead, modify and further analyze the genetic sequence. To determine if your efforts result in decreased long-term side effects, spin the wheel again.

**If you land on red/orange:** Your IND application was approved and no issues arose during clinical trial phases I-III, so you submit an NDA. However, your NDA is not approved due to troubles with mass-scale synthesis. You need to reevaluate the logistical practicality of producing this treatment. To determine whether your synthesis adjustments have worked, spin the wheel again.



## 5. Approved Treatments/Marketplace Issues

You have finally made it to the marketplace where your cancer treatment can be prescribed for patient use. Your discovery, obtaining funding, working through development, and obtaining FDA approval has taken a large amount of time, effort, and dedication. The ultimate test is on the horizon as your cancer treatment enters the marketplace, where many factors can influence its success.



To determine whether your treatment is regarded as a viable option, flip a coin...

If your quarter lands with tails up: Congratulations! Your cancer treatment has been successful in the patients who have been able to access it. Your cancer treatment is a recommended cancer treatment by most physicians and is at top of the marketplace. Place a tally in the 'effective cancer treatment' box.

If your quarters lands with heads up: Unfortunately, your cancer treatment has some mild side effects that a competing treatment does not produce. Gustavio Adolphonzo Pharmaceuticals has taken your cancer treatment off the market due to it being outcompeted. Sadly, you are back to the process of discovery. Place a tally in the 'ineffective cancer treatment box'.



# Marketplace Results

Effective Cancer Treatment	Ineffective Cancer Treatment
THE	

