Connecting Industry to Mathematics Instruction
NSF ATE Award # 1954291

Subcutaneous Drug Delivery Implant
Student Activity Sheet

In partnership with

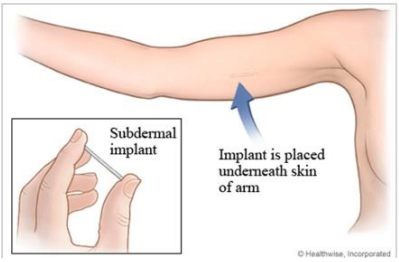
WAKE TECH

WAKE COUNTY PUBLIC SCHOOL SYSTEM

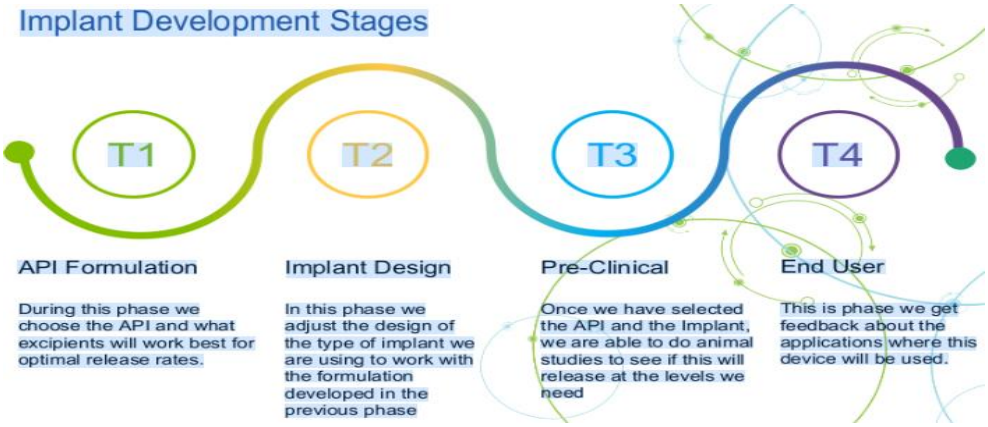
WakeEd PARTNERSHIP

A research associate at RTI helps to develop study designs, runs studies in the lab, collects data on a daily basis, runs all types of assays on the samples collected, analyzes data, and suggests changes to the study designs based on the data that is collected.

One thing that is being developed is an implant to disperse medication over a period of time to reduce the number of doctor visits needed, specifically for women in developing countries.



As a research associate for RTI, your job is to determine which Excipient (an inactive substance that serves as the vehicle or medium for a drug or other active substance) is best suited to use for the specific Active Pharmaceutical Ingredients (API). We need to see how much each combination releases on a daily basis. We will test this for 30 days. In order to be effective, the API “x” must stay above a minimum release rate of 20 ug/day and stay below the maximum release rate of 40 ug/day.



We will be focusing on T1 and T2.

T1 – API Formulation: As a research associate, your next steps will be to design a study, implement the study, collect data, and analyze/interpret the data.

Task 1: Design and Implement a Study

1. If you were designing this experiment, what are three elements you would include in your design? Please elaborate on your reasoning for your inclusions.

We will need to combine the one API "x" with the excipients available for subcutaneous (situated or applied under the skin) drug delivery in 4 different excipients. We need to see how much each API and Excipient combination releases the drug on a daily basis for a period of 30 days.

Remember, we want to reach a minimum API release rate of 20 ug/day and maximum API release rate of 40 ug/day for it to be effective.

Commented [1]: You could ask students why the researchers would want to set a minimum and maximum release rate.

For 30 days, we will place the combinations in an In vitro Study (occurs in a controlled environment) which will allow us to mimic the human conditions in which this drug/excipient combination will be exposed.

Commented [2]: Possible question: what is the purpose of the controlled environment in this experiment? This helps to ensure that the only difference in the treatment groups is the levels of excipient.

We will be collecting the sample daily (3 samples/3 times a day) to see how much drug has been released into the solutions to determine what is acceptable for this particular API.

2. What does RTI do in order to ensure that they have enough data to work with to give them the most accurate results?

Task 2: Data Analysis

Using the data collected for the 4 different Excipients by RTI's Lab Technician provided in the EXCEL worksheet (HERE), compute the following and record in the spreadsheet. For questions 3 and 4, include your results on your spreadsheet.

Commented [3]: On the excel sheet you need to label the first row with days.

3. For each excipient:
   a. Calculate the mean API release.
   b. Calculate the standard deviation API release.
   c. What do the mean and standard deviation tell you about the APIs?

4. Graph the daily release points complete with axes labels and titles. Decide the best graphic type to use. Include:
   a. Low acceptable release drug limit
   b. High acceptable release drug limit
   c. What type of graph is most useful? Explain your reasoning?

Commented [4]: Perhaps you want to ask this question before you have them create the graph. At this point you have them create a line graph then ask them which graph is most useful. Maybe ask "What type of graph would provide you with the most useful information for analyzing the data.

5. Describe the data for each excipient.

6. What trends do you see in the data?

7. Given the data, which excipient best fits in-between the acceptable drug release limits for the API? Explain your reasoning.

8. Does the standard deviation ever help you eliminate an excipient? Explain.

Task 3: Interpret the Data

9. Create 95% confidence intervals for the average API release level for each excipient. Compare the margin of error for each confidence interval. Do these confidence intervals further support the acceptable excipients? Explain.

10. Create 95% confidence intervals for the proportion of API release levels that are within the lower and upper accepted levels for each excipient. Compare the margin of error for each confidence interval. Do these confidence intervals further support the acceptable excipients? Explain.

11. Which confidence intervals above, mean or proportion, are most useful in this context? Explain why?

12. What recommendation(s) would you make to RTI based on the results you've gathered? (Which excipients need more testing? Which excipients should be discarded?) Explain your reasoning.

Task 4: T2 – Implant Design

As a research associate, your next step will be to adjust the design of the implant. We will adjust the polymer (natural or synthetic material that the implant is made of that contains and releases the API) and the diameter of the device.

We want to know which polymer and diameter size will work with the combination of drug/excipient from the T1. (API's Acceptable Drug release limits must be in-between 20ug/day and 40ug/day.)

How would you design an experiment to determine which polymer and diameter size would be best to use if we have 3 different polymers and 3 different sizes that are recommended to consider?

1. For each polymer and excipient and diameter size:
    a. Calculate the mean API release.
    b. Calculate the standard deviation API release.

2. Graph the daily release points on a graph: Include:
    a. Low acceptable release drug limit
    b. High acceptable release drug limit
    c. API release amounts
    d. Titles and labels

3. What can you conclude from the data? What recommendation(s) would you make to RTI based on the results you've gathered? (Which polymers and diameters need more testing? Which polymers and diameters should be discarded?) Explain your reasoning.