DARK HORSE CONSULTING GROUP

BRANDON TRAN 2023-2024

Regulatory Writing Tool

BUSINESS CASE

- Cell & Gene Therapy (CGT) vs Biologics/Large-Pharma writing requirements differ and DHC is uniquely positioned to aid in the CGT specifics.
- DHC wanted to create their own templates to better suit the difference in requirements for the Cell & Gene Therapy Space
- I was pulled into the project to create the a Ribbon Toolbar to aid with the Template
- In addition to programming, I picked up roles to
 - Create a system that can be packaged and sold to external clients
 - Create custom solutions to common writing processes like Citations, Headers, and anything else I could think of

ROLES & RESPONSIBILITIES

- My colleague's role/responsibilities:
 - Generate Templates the different modules of the Regulatory Writing Process with the FDA
 - Communicate standards/preferences to me such as font color, heading size, etc.
- My role/responsibilities:
 - Generate Graphical Assets for the Ribbon Icons
 - Design the layout of the Ribbon
 - Develop VBA code for all the button assets
 - Figure out how to package and deliver this as a new offering that DHC can generate revenue from



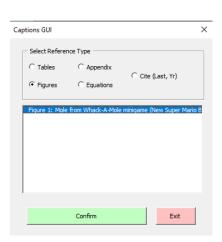
CITATION MANAGEMENT

- Finding all the tables, figures, equations, appendix headers, and even the citations in the bibliography is difficult
- Through my VBA code, I created systems to categorize, view, and even generate the direct reference to each citation element so that the writing process doesn't have to stop just to properly link these cumbersome objects

Figure 1: Mole from Whack-A-Mole minigame (New Super Mario Bros, Nintendo DS)



Here in Figure 1 I show the picture I used to image find & dominate the Whack-A-Mole minigame on my emulator of New Super Mario Bros. I used opency2 and <u>pyautogui</u> in Python to generate a clicking machine which would find and click all the moles without clicking any <u>Luigis</u> in the process!



ABBREVIATION GENERATOR

- After developing the bulk of generic features, I couldn't help but think "What would writers need?"
- Abbreviation generator utilizing Regex to find all unique 2+ acronyms in the document and generate a table for them
 - This is a very tedious process that can often result in a few words being overlooked now streamlined into a single button click

Here is a paragraph of acronyms such as CGT which stands for Cell & Gene Therapy. Though sometimes we specialize in certain subfields of CGT such as CTx for Cell Therapy or GTx for Gene Therapy. There's also a "hybrid" subset called GMCTx which is Gene-modified Cell Therapy which involves the gene-editing of your standard CAR-T cell to be a charged powerhouse cell. This modification requires vectors which often are AAV (Adeno-associated Virus) or LVV (Lenti Viral Vector) based as these are the popular two used in the industry.

LIST OF ABBREVIATIONS

