

Hand-on Short Course on Enhancing the DMC Package Using Opensource Software, AI, and LLMs

“Hand-on Short Course on Enhancing the DMC Package Using Opensource Software, AI, and LLMs” which I would like to give. I will be seeking input from Frank R., Frank H., and others.

The course will draw on the talks at the Global PV conference slides from the FDA speaker, Frank, and myself. The bulk of the course will dwell mostly on what is in the title and it would be hands-on to address the criticisms and issues that were raised recently on the issues with DMC packages and how to address these challenges leveraging opensource, AI, and LLMs. The draft content is outlined below.

The only question is would you be OK to have two courses offered by folks from AbbVie?

Please let me know if you are OK with this so I can get the abstract approved.

Thanks,

Melvin

Brief History of DMCs

Regulatory Guidance on DMCs

Challenges in Current DMC Packages

A Structured Approach in DMCs DMC Packages

Leveraging a Question-Based Approach

Quantitative Methods for Safety for Decision Making

Leveraging Visual Analytics

- Safety, Efficacy, Benefit-Risk

Examples of Some DMC Cases and Packages

Tools and Software for Efficient Generation of DMC Package

Model SDAC Package

- Static Outputs, Interactive Outputs, R Shiny Tools

Leveraging AI and LLMs in DMC Package Generation, Reporting, and Analysis

- ChatGPT, Claude, Perplexity, DeepSeek, Qwen, Gemini, Llama, Julius, Rstudio.ai, etc

R Exercises