**Project Statistician in Pharmaceutical Research**

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In the pharmaceutical industry, many statistical contributions in research are not regulated by authorities. Thus, the involvement of statisticians is of varying quality, appreciation, and quantity. Oftentimes, the statistician gets called in if an experiment does not show the expected outcome or turns out to be more difficult to analyze than anticipated.

Our vision is different to the reality: A statistician thoroughly plans the experiment regarding, e.g., the sample size in combination with effect size and read-out of interest, the randomization process, blinding concepts, and timing of readouts. After the successful conduct of an experiment, the statistician performs the suitable and at best pre-planned statistical analysis and reports the results in a well interpretable and translatable manner.

In the vision, the project statistician has access to all experiments that characterize a compound. Thus, she can also combine all results (different readouts and/or different experiments) and add a risk assessment of possible decisions of developing the candidate further or discarding it.

Within Bayer, we were able to start a pilot which involved statisticians and data scientists early in the process of compound characterization. The learnings from this pilot are the topic of this talk.

**Goals**

We wanted to plan and analyze all experiments within the project and display the results as comprehensively as possible, giving a maximized data insight to support a data-driven decision on the future of the compound.

**Challenges**

Getting access to all relevant data and transforming the data into a meaningful structure (also adding relevant meta data) took time and effort. In the end, only a subset of experiments was available, access to experiments labelled “unsuccessful” was not supported.

As the intention of the statistical involvement was not communicated clearly to all parties involved, getting a seat at the table of the project team turned out to be challenging.

As always, for the researcher it takes additional time to brief the statistician and align with her.

**Successes**

An excel template generator was created by the data science department to implement a minimum of consistent data structure for now and for the future.

The combination of similar read-outs across experiments from the statistician added to the data insight and was highly appreciated by lab head and management.

**Lessons Learned for the future**

The task needs to be assigned from research management and aligned on every level. The benefits of early involvement need to be clear from the beginning, as the time investment from a researcher who performs under immense time pressure needs to be justified. A success story will help to motivate future work for **Project Statisticians**.