

Applying DoE to Bioassays: Faster Optimization, Relevant Performance, Better Decisions

Dr. Swetlana Berger
Early Development & Gene Therapy

UCB Biosciences

Monheim am Rhein, Germany

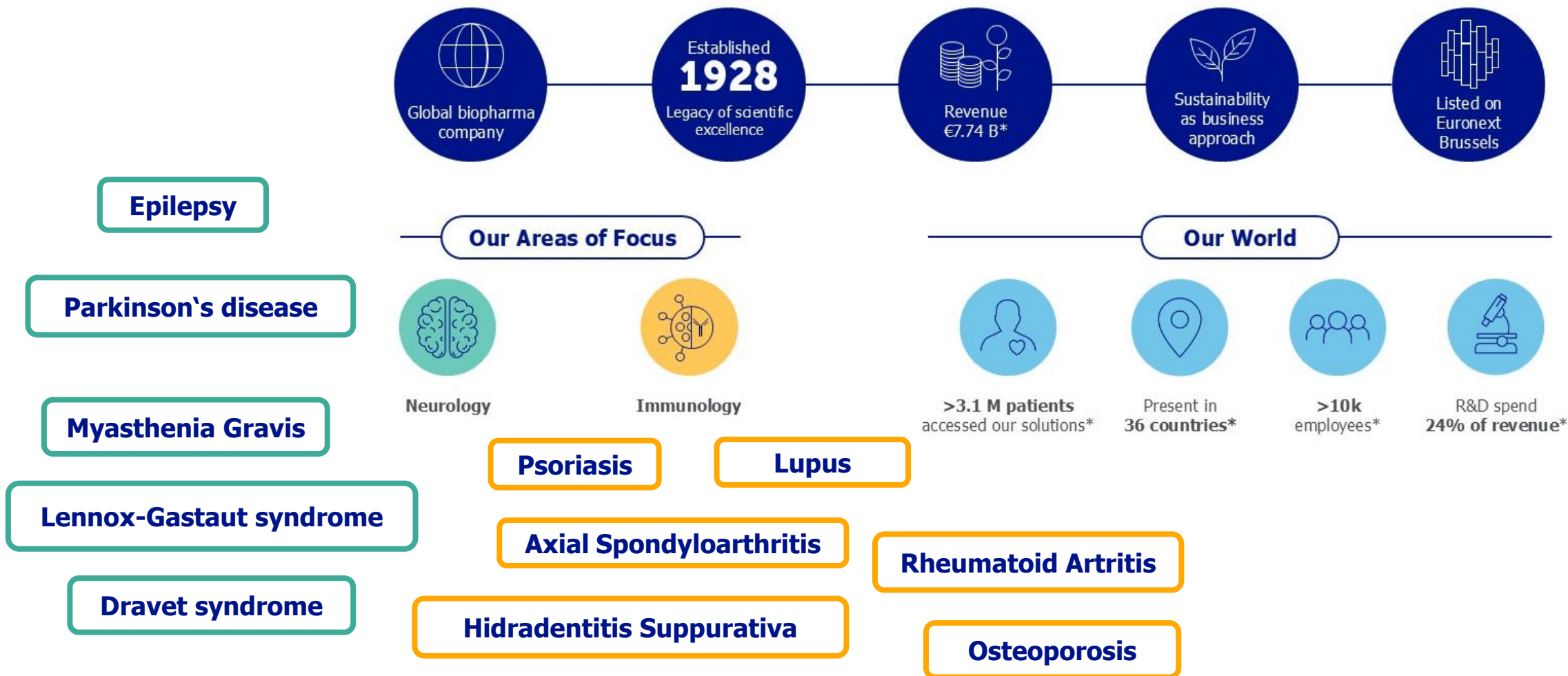
Non-Clinical Statistics Conference
Padua, Italy / 23 – 25 September 2026



Inspired by **patients.**
Driven by **science.**



UCB in a nutshell ...



Design of Experiment approach

- **What** : methods allowing to plan and analyse experiments

DoE is a way to approach real life question, in order to help answering them using numerical methods

**DoE:
what & why ?**

- **Why** : understand and/or optimize an experimental system

All possible influential factors are investigated in one single (bigger) experiment, providing additional information (e.g. interactions)

Statistical work in non-regulated environment

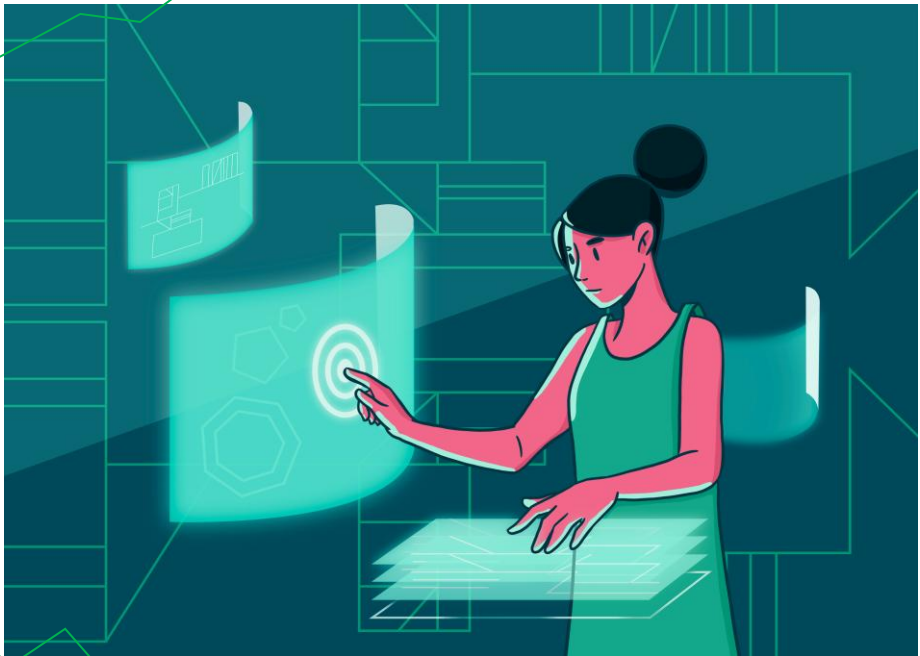
In non-GxP development the involvement of statistician is not mandatory



**Lack of innovative
stat methods**

**Increased efficiency
and as consequence
time savings**

**Reduction of
costly draw-
backs in assay
development**

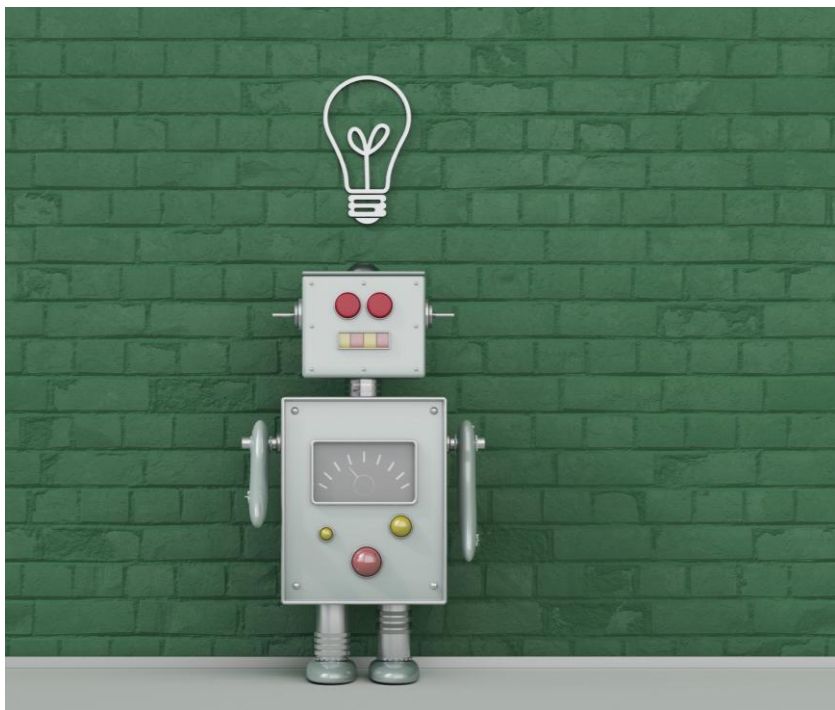


**First-time-
right results**

Added value from involvement of statistician from early stage on need to be shown to developer

Statistical work in non-regulated environment

Our Strategy: work on pilot projects

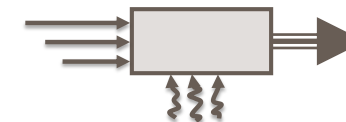


Developer participated on pilot projects are acting as multiplier's to the rest of the developer team

Review of DoE process flow: Step 1

Science

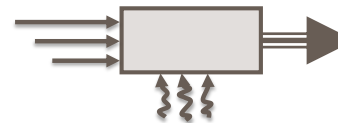
- Objectives/ success criteria definition
- Factors/Responses selection (Input-Outputs)



Review of DoE process flow: Step 2

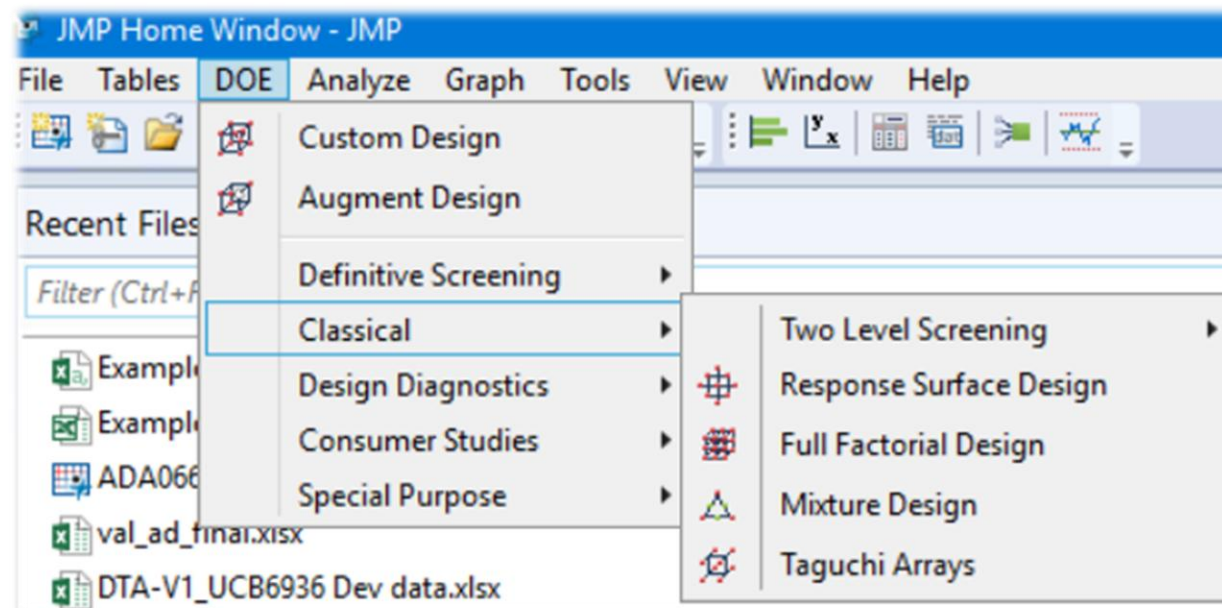
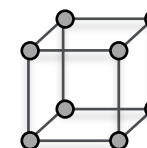
Science

- Objectives/ success criteria definition
- Factors/Responses selection (Input-Outputs)



Stat

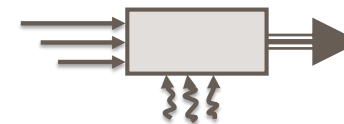
- **Choice / Creation of the experimental design**



Review of DoE process flow: Step 3

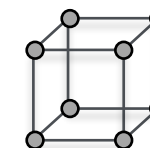
Science

- Objectives/ success criteria definition
- Factors/Responses selection (Input-Outputs)



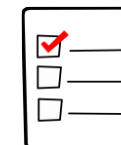
Stat

- Choice / Creation of the experimental design

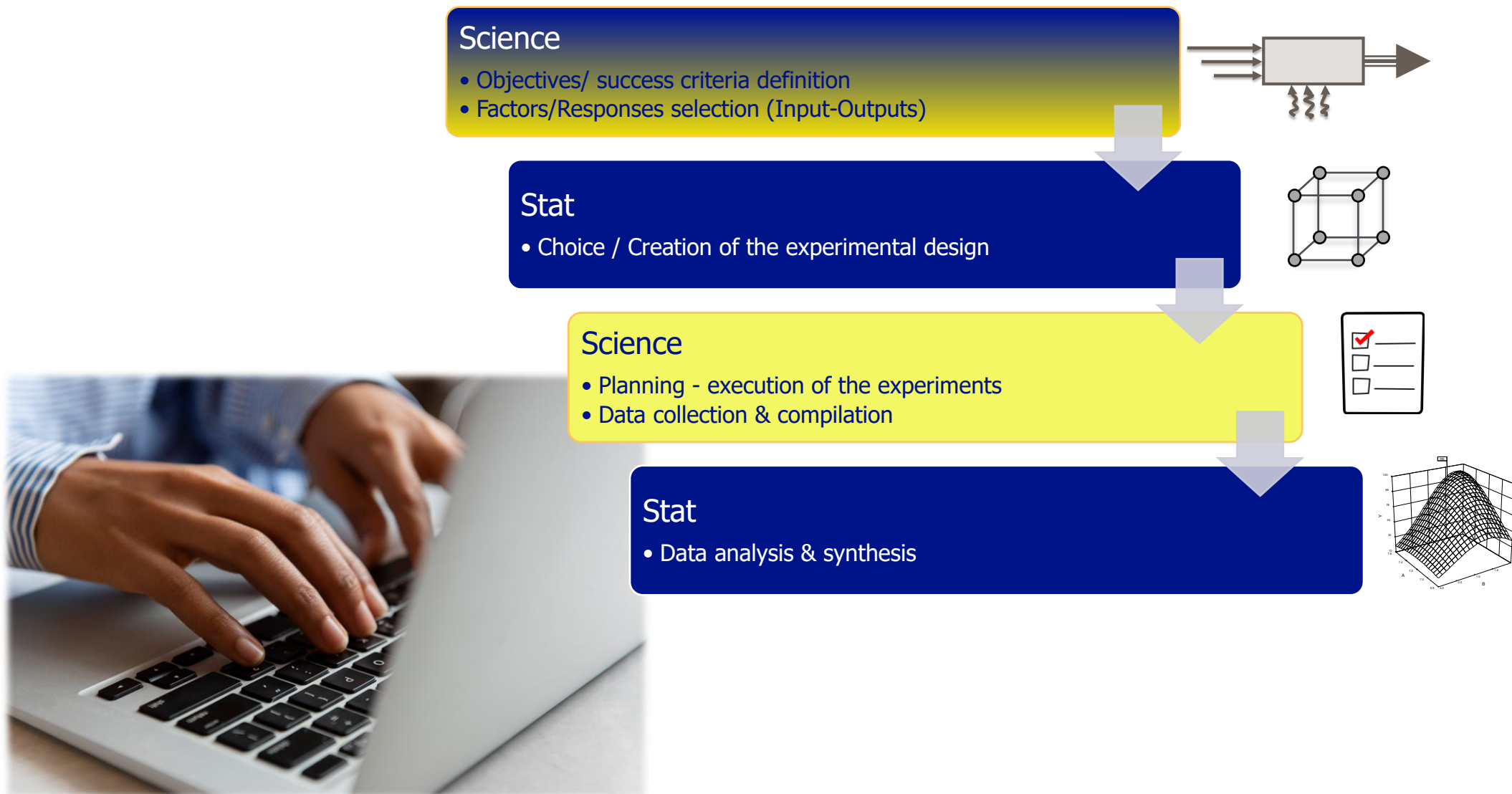


Science

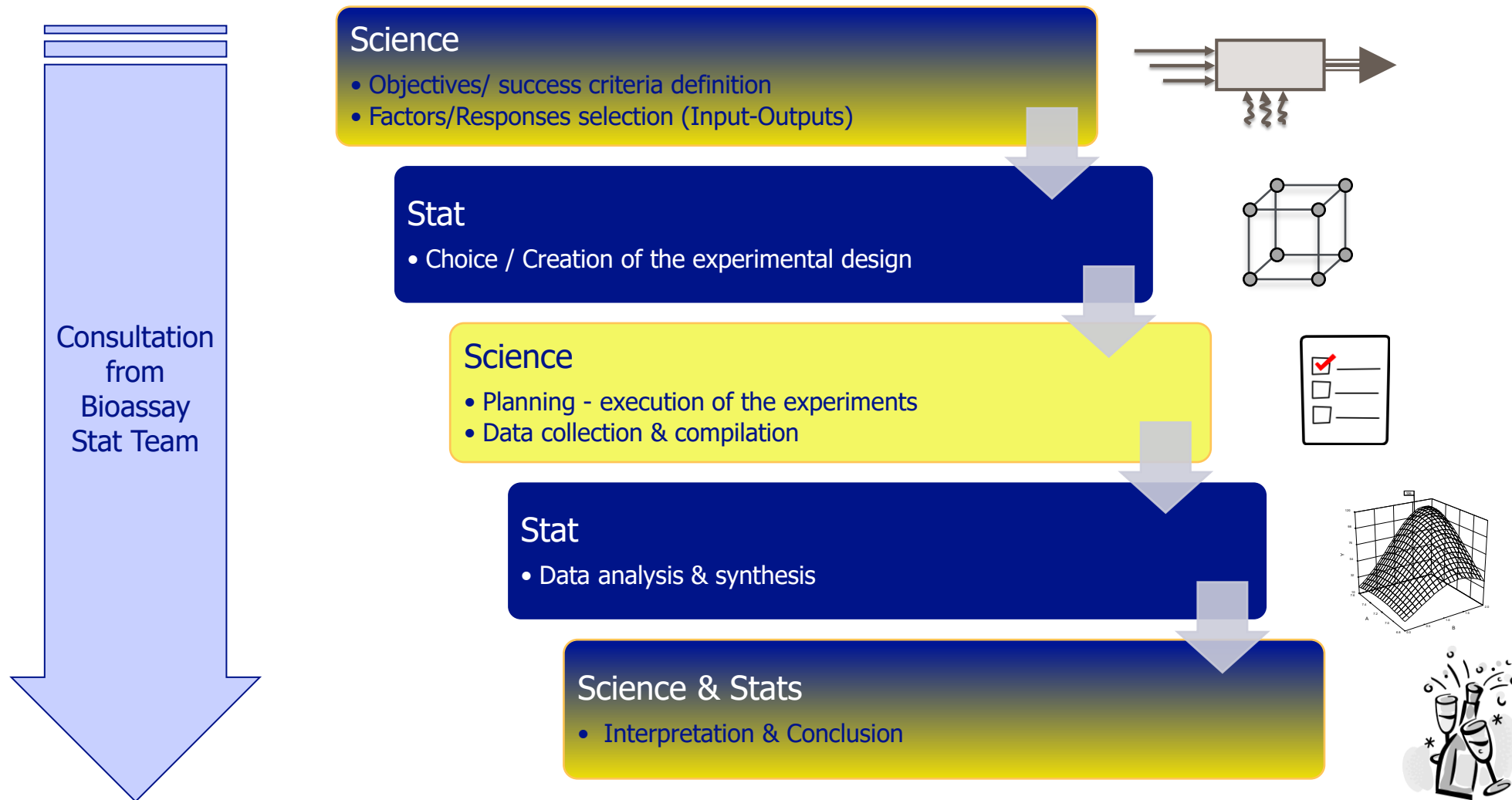
- **Planning - execution of the experiments**
- **Data collection & compilation**



Review of DoE process flow: Step 4



Review of DoE process flow: Step 5



Take-away's

Why

- DoE provides robust conclusions that serve business decisions
- DoE does not necessarily involve less experiments than OFAT (short term perspective)
- However, DoE provides a higher quality information (better precision, whole picture) right the first time (less rework)

How

- Pilot studies showed some few positive examples of collaboration of developer & statistician
- A way to introduce use of DoE on a large scale is to enable developers to manage the whole flow in semi-autonomy, consulting statistician when needed



Inspired by **patients.**
Driven by **science.**

Thanks for listening!