



# STATISTICS & PROGRAMMING

## OUR EXPERTISE

### 1. DATA MANAGEMENT SUPPORT

- SDTM
- Data integration & standardization
- Patient data listing
- Medical review listing
- Patient profiles

### 2. PROGRAMMING

- ADAM
- TLGs
- SAS programming
- SAS macro generation
- R programming
- R package generation
- Python

### 3. STATISTICS

- Study design & consulting
- Power analysis & sample size calculation
- Adaptive designs
- Bayesian designs
- Randomization
- Statistical analysis plans
- Statistical analysis
- Meta-analyses
- Clinical study report review
- Unblinded interim analysis (DSMB)
- Regulatory agency discussions

## OUR WORKFLOW



#### CONSULTING

- Sample size
- Synopsis / Protocol Statistical part
- Statistical Methodology



#### ANALYSIS PLAN

- Statistical Analysis Plan
- ADaM and TLF specifications



#### STATISTICAL ANALYSIS

- Interim analysis
- Final analysis
- ADaM and TLF programming



#### REPORTING

- Statistical Report
- Final TLF production



#### PRESENTATION

- Statistical input into
- Manuscript
- Poster
- Slides

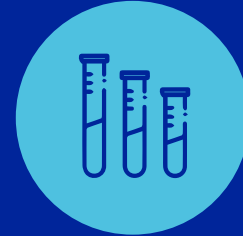
# TEAM OF EXPERTS

30+ Years Biostatistics Expertise



## 46 MEMBER TEAM

33 Statisticians & Stat Programmers  
13 Stat Programmer



## 13 YEARS EXPERIENCE IN AVERAGE

High level of task-related expertise,  
with up to >30 years of experience



## STATISTICIANS: MASTER+ PROGRAMMERS: BACHELOR+

Our Statisticians have a Master/PhD  
in Statistics or Mathematics  
Programmers have a Bachelor in  
a programming related field

## MULTIPLE THERAPEUTIC AREAS AND PHASES

Experience with clinical studies  
across therapeutic areas and  
phases:

- Phase I to IV, late phase
- Oncology, Infectious disease,  
CNS, Hormonal Disease, Meta-  
bolic Disease, Nutrition...

## CASE STUDY: PROGRAMMING OF SDTM



### CHALLENGE

20 clinical trials were performed in >20 countries  
on one common protocol with local (Country)  
adaptations over 4 years.

### SOLUTION OFFERED

Same edc platform was used for all trials and  
the programming was performed in modules  
for each domain with global macro parameters.

### BUSINESS IMPACT

Global protocol adaptations could be incorporated  
within very short amount of time.  
Local adaptations were handled easily and flexible.

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