



Statistics & Programming

WHAT IS S&P?



YOUR STATISTICAL PROGRAMMING CHALLENGES

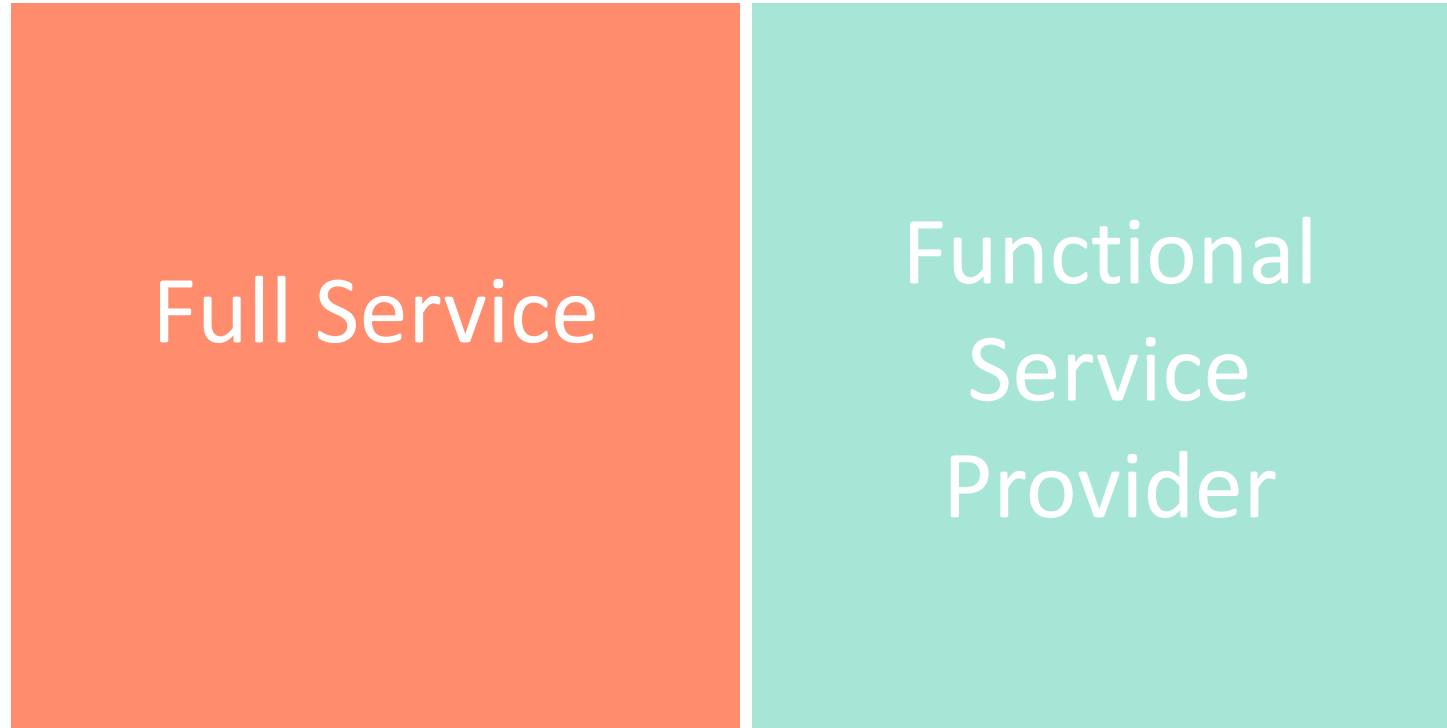
Challenge

You are looking for a cost competitive service provider offering commodity CRO services in units of time

Solution

Excelya is a knowledge provider and pharma innovator. We are your reliable partner in consulting, planning, analysis, reporting and presentation.
We take care of your data!

BUSINESS LINES



Full CRO capabilities
All study phases (I to IV)
All therapeutic areas

All functional capabilities across tailor-made programs

IMPROVED QUALITY, COSTS AND TIME

1 Ensured quality

Staff are very experienced, **capitalizing on knowledge, experience and training.**

Staff **master all tasks and integrate all changing standards** (processes/ organization/ tools/ guidelines).

2 Decreased costs

Cost reduced with **gain in expertise, optimized processes.**

Activities accelerated that can be automated or standardized.

3 Meet timelines

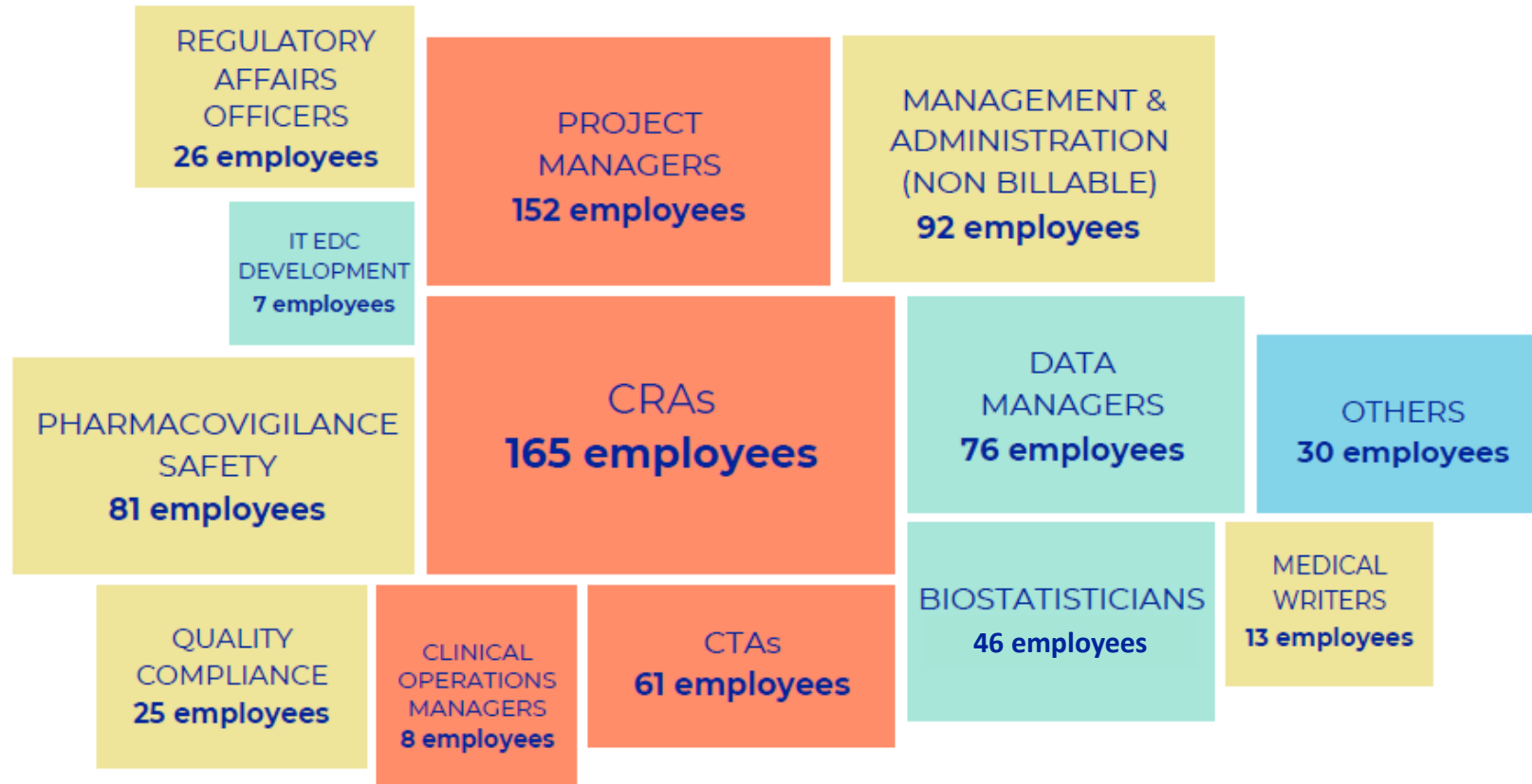
Staff are **fully operational** for each study in a short time.

Strong teamwork to help out in case of tight time constraints.

Synergies created cross therapeutical areas for the same tasks or within study programs.

OUR EXPERTS

800 permanent staff



30+ Years Biostatistics Expertise

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S&P ORGANIZATION

Michael Pfitzenmaier

Etienne Gransard
France

15 Excelyates

7 Senior Statisticians
3 Statisticians
4 Senior Programmers
1 Programmer

Silke Hörsch
Germany / Greece

31 Excelyates

19 Senior Statisticians
6 Statisticians
6 Senior Programmers

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

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, Metabolic Disease, Nutrition...

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

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OUR EXPERTISE

Data Management Support

1

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

Programming

2

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

Statistics

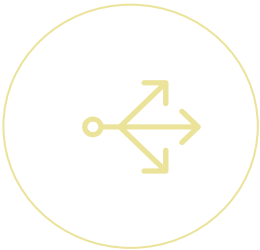
3

- Study design and consulting
- Power analysis and 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
-

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AREAS OF INNOVATION

#01



Automation /
Standardization of TFLs

#02



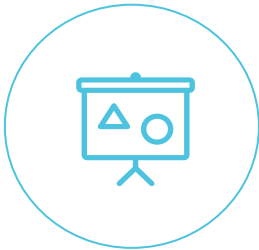
SDTM semi-auto
generated from EDC

#03



Risk-based statistical
monitoring

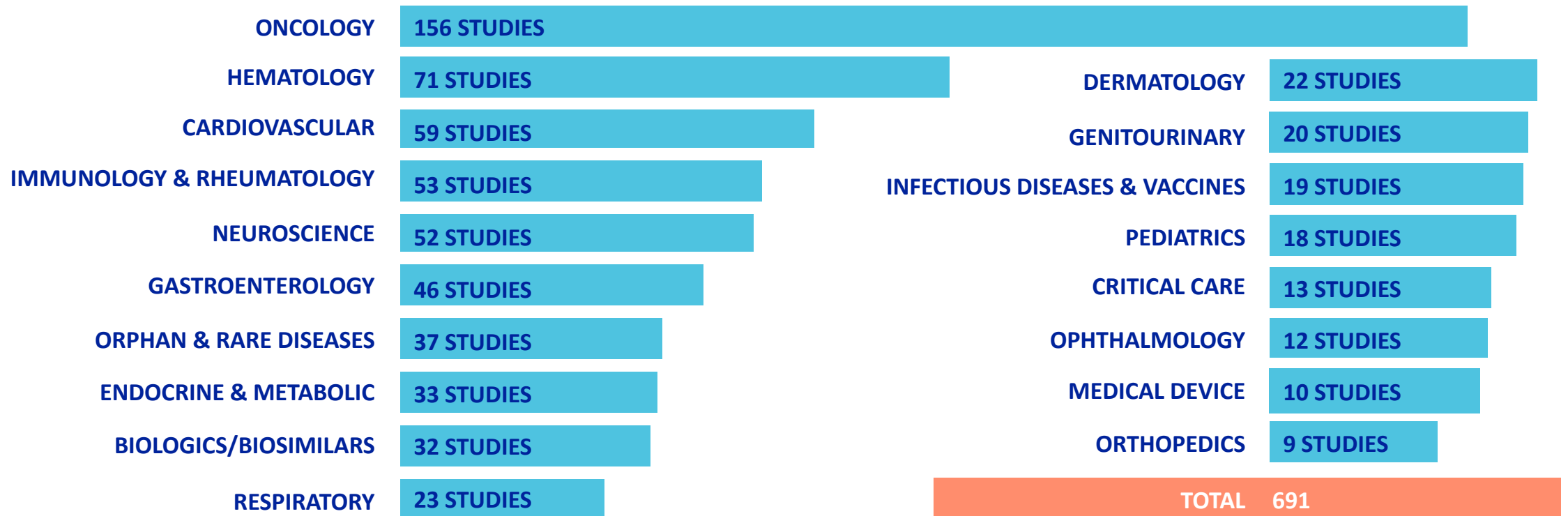
#04



Data visualization/
exploration

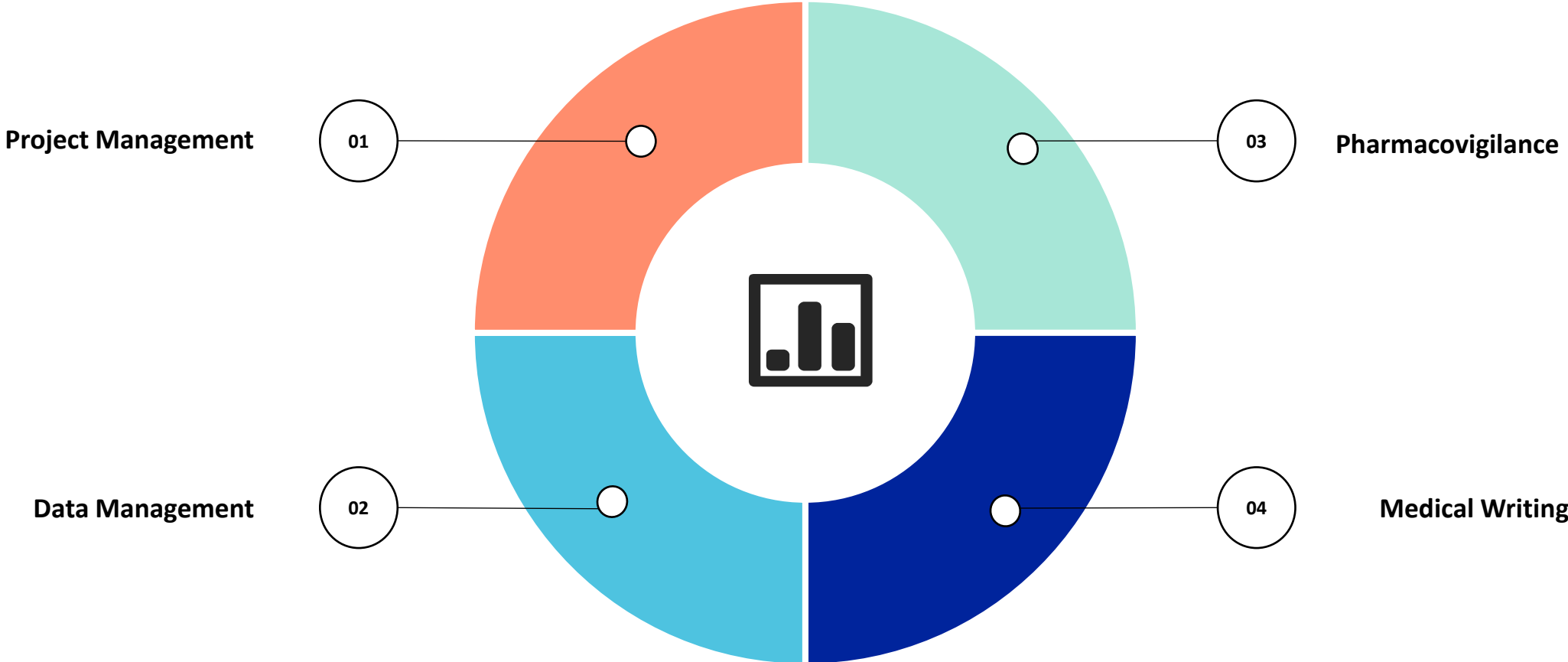
STUDIES FOR THE LAST THREE YEARS

We cover phase I to IV trials, non-interventional and observational studies and adaptative desings, and cover a wide range of therapeutic areas:



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COLLABORATION WITH ALL DEPARTMENTS



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Thank you