

# Statistics vital for new drugs

In the pharmaceutical industry, the use of statistics as a method for R&D is steadily gaining importance. With 61,000 employees and operations in over 100 countries, AstraZeneca is no exception. The company has a staff of some 80 statisticians in Mölndal, Sweden who analyse and evaluate new pharmaceuticals in the fields of cardiovascular (heart/blood vessels) and gastrointestinal (stomach/intestines) medicine. In order to deal with peak periods and to develop their methodology, they have collaborated with Statistikkonsulterna for seven years.

## **A common network for key competence**

Anders Carlqvist, Director Statistics and Programming Capability at AstraZeneca in Mölndal, Sweden says that they are one of the largest private employers of statisticians and not only in Sweden but in all of northern Europe. The search for the right skills is constantly underway and Statistikkonsulterna have become a strategic partner for external competence and for new recruitments.

“Statistikkonsulterna have the ability to see our needs, work independently and to provide creative solutions. This has formed the basis for collaboration that is beneficial to both parties. We have found a flexible resource that can deal with the peaks and troughs in our projects. These consultants are also an important source of recruitments for us,” says Anders Carlqvist.

The demands on statisticians working in the pharmaceutical industry are high. There is no margin for error when evaluating global studies whose results ultimately pertain to peoples’ health—a matter of life and death. Research skills and experience in clinical studies are basic prerequisites. AstraZeneca and Statistikkonsulterna have supported each other in the effort to match needs and skills in operations that vary considerably. Over the years, we have seen people go in both directions; from a consultant’s role to being employed at the company and vice versa. We invest in our staff’s training and through our collaboration, we keep the skills within the network.



foto: Mikael Kristenson



Foto: Johan Jarneving

*Anders Carlqvist is Director for Statistics and Programming Capability at AstraZeneca in Mölndal, Sweden.*

In addition to the client-consultant relationship, AstraZeneca and Statistikkonsulterna have close contacts with the university and are active in The Swedish Society for Medical Statistics. Both companies also take part in an annual statistical conference.

“We are part of the same network and work in the same area but have different roles. This enables us to complement one another nicely. In addition to the consultants working in ongoing projects, we have also taken part in some special projects and method development,” says Statistikkonsulterna’s CEO Mats Rudholm.

**“Statisticians are a fraternity with obvious scientific training and rigorous demands for correctness.”**

**From study statistician to being responsible for global pharmaceutical projects**

The statisticians at AstraZeneca have different roles. Study statistician is a professional title for anyone who does practical planning, analysis and compiles reports in individual studies. They also conduct evaluations of external data.

Project statisticians have a more comprehensive role and are involved in several studies within the framework of the same project. Those with the title Global Product Statistician (GPS) have the ultimate responsibility and a coordinating role. They are responsible for all research conducted on a pharmaceutical on a global level.

“We have approximately 45 GPSs; one for each pharmaceutical project. Each GPS is responsible for a budget on the scale of a mid-sized Swedish corporation and considering their role, they would be part of the executive management team at a company of that size. Here, they manage projects with a global scope that involve thousands of people,” says Anders Carlqvist.

Operations at AstraZeneca are divided into five therapy areas: respiratory/inflammation, oncology/infection, cardiovascular, gastrointestinal and neuroscience and each area

has a head statistician.

The statistics are generic in many respects but it is nonetheless essential to have an understanding of their application. The statistician contributes more than significances. We add logical thinking and ideas to the actual formulation of the problem.

**Guiding professional ethics**

Developing a new drug is a long, expensive and complex process. Research is controlled by detailed regulatory requirements from governmental agencies, lead by the US Food and Drug Administration (FDA). The EU’s equivalent, the European Medicines Agency (EMA) is also an important body. Basic statistical data is one such regulatory requirement.

The duration of a patent is limited and a company’s earning capacity depends entirely on its capability to bring a drug to the market safely and efficiently. It is at the end of phase two and during phase three of a research project—when a discovery is studied and confirmed—that statistics are most vital.

“The objective is a balance between safety and effect in which mathematics and statistics play an increasingly important role in the development of a drug. All pharmaceutical companies want to, or actually must, base their decisions on quantitative data and evidence-based studies,” says Anders Carlqvist.

In the effort to strike this balance, he sees the statistician’s professional honour as a guarantee for ethics. Statisticians are a fraternity with obvious scientific training and rigorous demands for correctness.

“The statistician currently plays a vital role in clinical testing but I think that they could make an appreciable contribution even at the explorative stage.”

The statistician’s increased importance and scientific code of honour are things that Statistikkonsulterna would agree about. Measurability and quantitative testing are becoming increasingly important for decision-makers in many industries. There are currently five consultants working at AstraZeneca and the collaborative efforts to evaluate safety and effect for the drugs of the future continue. ■

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