Drug Information Journal, Vol. 33, pp. 407–415, 1999
Printed in the USA.

0092-8615/99

QUALIFIED STATISTICIANS IN THE EUROPEAN PHARMACEUTICAL INDUSTRY: REPORT OF A EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY (EFSPI) WORKING GROUP

EFSPI WORKING GROUP,* Isleworth, United Kingdom

Regulatory guidelines assume that the responsibility for all statistical work associated with clinical trials will lie with a statistician who should be qualified by education, training, and experience to perform this task. As different European countries have widely differing educational systems and varied experiences of applying statistics in the pharmaceutical industry, it is difficult to develop a clear, unambiguous Europe-wide definition of the desired profile of such a statistician. There is a broad consensus, however, that an appropriate background would include a university degree in statistics or equivalent qualification, plus more than three years of experience in medical statistics. An example of an equivalent qualification would be a degree in mathematics or a related subject, involving more than one year (full-time equivalent) of courses in statistics.

It is hoped that this outline definition will give guidance to companies, to regulatory authorities, and to individual statisticians in terms of providing statistical support to clinical trial and other pharmaceutical development activities and that it may provide a foundation for future development of the statistical profession within the pharmaceutical industry.

Key Words: Regulatory affairs; Pharmaceutical industry; Statisticians; Qualifications

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Reprint address: David Morgan, Director of Statistics and Data Management, AXESS Limited, John Busch House, 277 London Road, Isleworth, Middlesex TW7 5AX United Kingdom.

*The EFSPI Working Group is comprised of: David Morgan, MA, MSc, CStat, formerly Head of Biometrics and Data Management, Hoechst Marion Roussel, Denham, United Kingdom (chairman); Antonella Bacchieri, MSc, Head of Biostatistics and Data Management, Sigma-tau, Pomezia (Rome), Italy; Claus Bay, MSc, Head of Statistics and Data Management, Leo Pharmaceutical Products, Denmark; Erik Cobo, MD, PhD, Lecturer in Biostatistics, Department of Statistics and Operational Research, Universitat Politecnica de Catalunya, Barcelona, Spain; Peter van Ewijk, MSc, Group Head, Biometrics, NV Organon, Oss, The Netherlands; Bernhard Huitfeldt, PhD, Director of Biostatistics and Clinical Information Systems, Astra Arcus AB, Sodertalje, Sweden; Jean-Christophe Lemarié, Dip Stat, MSc, Head of Biometrics and Data Management, Hoechst Marion Roussel, Paris, France; William Malbecq, DSc, Associate Director, Biostatistics, Merck, Sharp and Dohme (Europe), Brussels, Belgium; Willi Maurer, PhD, Head of Biostatistics Europe, Novartis Pharma AG, Basel, Switzerland; Peter Morse, BSc, Dip Stat, CStat, Head of Medical Statistics, Scotia Pharmaceuticals Ltd., Guildford, United Kingdom; Horst Nowak, Dr Rer Nat, Head of Biometrics, ASTA Medica AG, Frankfurt, Germany; and Hans-Joachim Trampisch, Dr Rer Nat, Head of Department of Medical Informatics, Biometrics and Epidemiology, Ruhr-Universität Bochum, Germany.

BACKGROUND

THE DEVELOPING ROLE of statisticians in the pharmaceutical industry has resulted in over 2000 statisticians being employed in Europe within pharmaceutical companies and contract research organizations, chiefly working on clinical trials (1). European regulatory authorities are employing an increasing number of statisticians in order to facilitate statistical review of marketing authorization applications (2,3). European Good Clinical Practice (GCP) Guidelines state that: "Access to biostatistical expertise is necessary before and throughout the entire trial procedure, commencing with designing of the protocol and ending with completion of the Final Report . . . The planning of the analysis and its subsequent execution must be carried out or confirmed by an identified, appropriately qualified and experienced statistician" (4).

The International Conference on Harmonization (ICH) E6 GCP guideline (5) is a little less explicit, but carries the same clear message. One of the principles of ICH GCP is stated to be that: "Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s)" (Section 2.8). It is further stated that: "The sponsor should utilize qualified individuals, (eg, biostatisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial process, from designing the protocol and CRFs and planning the analyses to analyzing and preparing interim and final clinical trial reports" (Section 5.4.1).

The ICH E9 guidance on Statistical Principles for Clinical Trials (6) emphasizes the importance of statistical input to the design and analysis of clinical trials and states that: ". . . it is assumed that the actual responsibility for all statistical work associated with clinical trials will lie with an appropriately qualified and experienced statistician, as indicated in ICH E6. The role and responsibility of the trial statistician, in collaboration with other clinical trial professionals, is to ensure that statistical principles are applied appropriately in clinical trials supporting drug development. Thus, the statistician should have a combination of education/training and experience sufficient to implement the principles articulated in this guidance" (Section 1.2). The final sentence is reproduced to provide the glossary definition of a trial statistician.

These extracts immediately raise the question of what qualifications and experience make an individual appropriate for such work. In countries such as the United States, Canada, and the United Kingdom, degree programs in statistics have existed for some time, leading to a clear concept of a statistician's skills and role. In Germany and the United Kingdom some attempt has been made to define the experience necessary to provide professional accreditation for statisticians. There is, however, no common European-wide understanding of what it means to be "an appropriately qualified and experienced statistician."

The European Federation of Statisticians in the Pharmaceutical Industry (EFSPI), therefore, decided to set up a working party to review this area, with the following aims:

- To document the range of qualifications and experience of individuals regarded as "qualified statisticians" for the pharmaceutical industry of each European country affiliated with EFSPI,
- To investigate the feasibility of developing national guidelines for "qualified statisticians," and
- To investigate the feasibility of developing common European guidelines for "qualified statisticians."

This paper represents the output of the working party. The opinions expressed are those of EFSPI and of the working party members and do not necessarily represent the views of the companies employing the authors.

It was recognized that similar issues arise for statisticians in the nonclinical area. For example, Good Laboratory Practice requires that all individuals engaged in nonclinical laboratory studies: ". . . shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions" (7). The working party, however, restricted its attention to medical statisticians engaged in clinical trials.

A common understanding of the concept of the qualified and experienced statistician was anticipated to yield a number of benefits. Individual statisticians within the pharmaceutical industry would benefit by gaining "professional identity" and an incentive to undertake further training. Pharmaceutical companies would benefit through improved recruitment practices, enhanced quality of statistical work, and easier assessment of the capabilities of contract research organizations. Regulatory authorities and society would gain a better quality of clinical research through improved statistical work. Universities could gain guidance for course development to enable them to better serve the pharmaceutical industry.

STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY

Despite increasing emphasis being placed upon the globalization of the pharmaceutical industry, due to commercial pressures and the influence of regulatory initiatives such as the ICH, there are still striking differences in the number and nature of statisticians working in the industry in different European countries. One source of diversity is the wide variety of university educational systems in Europe (8,9). The appendix contains descriptions of the current status of the statistical profession within the pharmaceutical industry in each country represented in EFSPI.

THE CONCEPT OF THE APPROPRIATELY QUALIFIED AND EXPERIENCED STATISTICIAN

Framework for Definition

The skills and knowledge required by a statistician in the pharmaceutical industry include those defined by Lewis (10). He suggests that effective statisticians need a strong technical foundation and knowledge of the pharmaceutical context, plus skills in communication and project management. These attributes would clearly be gained through a mixture of education, other technical training, and relevant experience.

The working party agreed that the elements necessary to define a "qualified medical statistician" were as follows:

1. *A University Qualification with Appropriate Statistical Content (or Equivalent).* Given the many different educational systems involved across Europe, statistical content could be defined in a common way in terms of full-time equivalent (FTE) years of statistics; thus, a five-year course with 30% statistical content and a three-year course with 50% statistical content would both represent 1.5 years FTE in statistics, and
2. *Appropriate Experience in Medical Statistics.* It was judged that experience in the pharmaceutical industry was not necessary, but experience in medical statistics, involving clinical trials and associated regulatory requirements, was needed.

A 'Common Core' Definition

The working party agreed to publish the "concept" of a qualified statistician rather than rely on formal accreditation or other quasi-legal framework. It was noted that there was about 80% of "common core" within local schemes (proposed or in operation). This could be summarized as: "A 'qualified medical statistician' is expected to have a university degree in statistics or equivalent, plus more than three years of experience in medical statistics." An example of an equivalent qualification would be a degree in mathematics or a related subject, involving more than one year (full-time equivalent) of courses in statistics.

While inevitably being somewhat vague and lacking detail on what might be included in university courses, this definition does make certain things clear. First, it is not necessary for an individual's degree to be in

statistics, provided that it has a suitable statistical content. Second, a degree in medicine, with only a small number of courses in statistics, would not entitle someone to be regarded as a qualified medical statistician.

In addition, the generality of this definition gives the advantage that it is not restricted in application to Europe, or to the clinical arena. It could easily be adapted to use in North America or Asia, or to nonclinical statisticians.

In developing guidelines, however, it was recognized that many good pharmaceutical industry statisticians would not meet the definition adopted, due to lack of formal statistical qualifications, and that exceptions would need to be catered for on a transitional basis. In addition, statisticians should not rely purely on material covered in their degree program, but should ensure that they keep up to date with developments in the area by attendance at training courses, conferences, and other forms of continuing professional development.

PROBLEMS OF FORMAL ACCREDITATION

Within the United States context Imrey (11) and discussants have outlined arguments for and against certification schemes. Imrey promoted certification, meaning an optional process by which individuals can achieve professional recognition for statistical knowledge and achievement. He distinguished this from accreditation of academic programs and from legal licensing of practitioners, with which it is sometimes confused.

Opinion was divided among pharmaceutical statistics organizations in Europe on the desirability of having a formal certification scheme for pharmaceutical statisticians. Regardless of desirability, it was felt in general that it would not be feasible to implement such a scheme across Europe in the short term. There were several reasons for this:

1. Some countries were firmly opposed to the idea of certification in principle,
2. Consensus was not achieved on the detail of the desirable profile of a pharmaceutical industry statistician,
3. If such a profile were agreed upon, it would be difficult to judge suitability of qualifications because of the variety of different educational systems within Europe,
4. In addition, many good pharmaceutical industry statisticians would not meet the desired profile, leading either to a discrediting of the process or to large numbers of exceptions, and
5. Procedures would need to be established for recertification and defining criteria under which individuals should lose their accreditation. There could be legal implications in this.

It is felt, however, that any national schemes developed for recognition of pharmaceutical industry statisticians should be closely related to the common core definition above, thus easing any mutual recognition process which might be developed in the future. Once such a process was in place, countries currently opposed to formal certification or accreditation might withdraw their opposition, making a unified European approach possible.

CONCLUSION

Different European countries have widely differing educational systems and history of applying statistics in the pharmaceutical industry. Hence, it is difficult to develop a clear unambiguous Europe-wide definition of the desired profile of "an appropriately qualified and experienced statistician" as required by regulatory guidelines to take responsibility for clinical trial work. There is a broad consensus, however, that such an individual would be expected to have a university degree in statistics or equivalent, plus more than three years of experience in medical statistics. An example of an equivalent qualification would be a degree in mathematics or a related subject, involving more than one year (full-time equivalent) of courses in statistics.

It is hoped that this outline definition will give guidance to companies, to regulatory authorities, and to individual statisticians in terms of providing statistical support to clinical trial and other pharmaceutical development activities and may provide a foundation for future development of the statistical profession in the pharmaceutical industry.

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APPENDIX: DESCRIPTION OF PHARMACEUTICAL STATISTICIANS BY COUNTRY

Belgium

About 10 pharmaceutical companies employ a total of approximately 65 statisticians. The companies are either Belgian or European/local operations of American and British companies. A few contract research organizations (CROs) employ approximately 10 statisticians working primarily for the pharmaceutical industry. Half of the pharmaceutical statisticians in Belgium have over five years of experience, with 10% having over 10 years of experience.

The vast majority of Belgian pharmaceutical statisticians have an MSc in statistics or in a related field (mainly mathematics) or an agricultural engineering degree. Approximately one out of six statisticians has a PhD degree in statistics or a related field. A few statisticians have a technical degree.

One Belgian university center (Diepenbeek) has offered a specific postgraduate degree in biostatistics since the early 1990s. MSc degrees in statistics are awarded by three universities and the majority of other universities give degrees in mathematics with specialization in statistics. The duration of the studies is four years minimum with one or two additional years for the postgraduate degrees.

Responsibilities of statisticians within companies include statistical design of clinical trials, analysis and reporting of results, plus participation in presentations and publications. Statisticians generally sign the protocol and the report, with both documents being approved by a senior statistician.

There is no scheme for professional certification of statisticians in Belgium. The drug regulatory authority does not employ any statisticians.

Denmark

About eight pharmaceutical companies employ approximately 50 statisticians, with around 80% of these working in the three largest Danish companies. A few CROs working partly or exclusively for the pharmaceutical industry employ statisticians, but this group numbers less than 10 in total. Experience in the industry ranges from zero to more than 30 years, but the majority has about 1–6 years, due to the tremendous growth in the area over the past decade. The number of statisticians in the pharmaceutical industry in Denmark has doubled during the 1990s.

The vast majority of Danish pharmaceutical statisticians have an MSc degree in statistics. There are some PhDs, but no BScs, as the BSc degree is very new in Denmark and most students go on to the MSc level. Some have a degree from the Technical University, where graduates can have up to the equivalent of 1.5 years of statistics.

The MSc degree in statistics was instituted at the University of Copenhagen in 1958 and can also be obtained at the Universities of Aarhus and Aalborg. The duration is five years, of which about half consists of statistics and the remainder of mathematics and computer science.

In Denmark the statistician participates in writing the protocol and is counted among the authors: in some companies the statistician signs the protocol. A named statistician is normally among the authors of clinical study reports, which are approved by the head of the statistics department or another senior statistician.

There is no certification of statisticians in Denmark. The drug regulatory authority does not employ statisticians for review of new drug applications.

France

There are around 150 statisticians in France within 32 pharmaceutical companies. In addition, at least 15 CROs working with the pharmaceutical industry directly employ statisticians. Traditionally, many pharmaceutical statisticians in France were medical doctors with additional training or experience in statistics. The statisticians currently recruited into the industry, however, are normally expected to have academic qualifications explicitly oriented toward statistics. There are various ways of achieving this:

1. Education specialized in statistics (four or five years after Baccalaureat or Bac + four):
   - The Institut de Statistique de l'Université de Paris and the Ecole Nationale de la Statistique et de l'Administration Economique provide a full curriculum in statistics over two or three years to students recruited at Bac + two,
   - A few universities have a Diplôme d'Etudes Approfondies (DEA) or a Diplôme d'Etudes Supérieures Spécialisées (DESS) in statistics; this involves a one-year course for students recruited at Bac + four among graduates in Mathematics (Maîtrise = MSc) or from Grandes Ecoles, and
   - One university has a Magistère in statistics, involving a three-year course for students recruited at Bac + two.
2. Other education with statistical content:
   - Some DEA, DESS, or Magistères in Mathematics or Economics in the universities may have a strong orientation toward statistics,
   - The Mathématiques et Applications aux Sciences Fondamentales and Maîtrise en Ingénierie Mathématique in the universities are Maîtrises (Bac + four = MSc) in Mathematics with a choice of options strongly oriented to statistics, and
   - Some Grandes Ecoles (Bac + five), especially in agronomy, may have a statistical content.

Training on the job under the supervision of senior staff is generally necessary for statisticians joining the pharmaceutical industry, although a 4–6 month placement in industry or research is included in most courses. There is no certification scheme for statisticians in France.

The French regulatory agency does not employ any statisticians, though frequent use is made of consultants from the Institut National de la Santé et de la Recherche Médicale.

Germany

In the German pharmaceutical industry statisticians are, in general, employed only in companies with their own research and development. Depending on internal company organization and size, statisticians can be found in preclinical fields (eg, pharmacology and toxicology), as well as in all phases of clinical trial work. In some companies statisticians will have responsibility for data management, as well as statistics. Over 100 statisticians are employed in pharmaceutical companies, with more than 70 employed in contract research organizations providing services to the industry.

The optimum profile for a pharmaceutical statistician would include applied statistics as primary subject, (theoretical) medicine as subsidiary subject, experience in SAS and EDP operating systems, plus basic knowledge in database systems. Some statisticians are employed in CROs, where their background and duties are comparable to those within the industry itself.

The background of a pharmaceutical statistician would usually include a university degree ("Diploma" after at least four years; the usual time is six years) in mathematics, statistics, or informatics, more rarely in psychology or education, and so forth. A PhD ("Dr.rer. nat." etc.) is not necessarily required. Most training occurs "on the job," as there has been no biometrical qualification at German universities.

It is standard to involve the statistician in the early planning phase of clinical trials. The statistician then takes responsibility for data management (depending on the company), analysis, and reporting, and usually signs the protocol and the study report. The type of cooperation for the report depends on the company: in some cases the statistician provides annotated tables or a statistical report, in other cases a truly joint medical and statistical report is produced. In many companies the statistician is involved in the Clinical Expert Report for a Marketing Authorisation Application, though usually without formal sign-off responsibility. The German standards for GCP (based on a German Society for Medical Informatics, Biometrics and Epidemiology memorandum) specify more details than European Union GCP!

Some 50 statisticians in the pharmaceutical industry (and around 40 others working in the medical area) have qualified as "Certified Medical Biometrician." The requirements are:

1. A university degree in medicine, statistics, or mathematics, at least three years of practical experience with biometrics in medicine and at least five years of further scientific education after the degree. The degree may be in another subject if there is proof of appropriate knowledge,
2. Theoretical scientific education involving medicine for mathematicians and statisticians and mathematical statistics for those qualified in medicine. Candidates then make a choice from mathematical statistics, special applications of biometrics in medicine, and numerical techniques/medical information processing,
3. Practical scientific education, involving two (out of seven) biometric working areas, demonstrated by successful projects, reports, or publications. Candidates must also produce a report on their own individual work in biometrics in medicine, and
4. Oral presentation, including a disputation demonstrating skills in the interdisciplinary work. The certification committee will choose one out of three titles given by the candidate.

The German regulatory authority (BfArM, Bundesinstitut fuer Arzneimittel und Medizinprodukte) employs two statisticians.

Italy

Italian pharmaceutical companies employ a total of around 70 statisticians. A small number of CROs, working primarily for the pharmaceutical industry, employ statisticians, though most of the CROs present in Italy are subsidiaries of multinational companies and offer only study monitoring and related services.

The vast majority of Italian pharmaceutical statisticians have a university degree in statistics (around 50%) or biology (around 30%). Other degrees can be mathematics, chemistry, medicine, or pharmacology. The Italian university degree is normally of four or five years' duration. Although the system differs from most others in Europe, Italian degrees in statistics and biology can be considered roughly equivalent to MSc degrees. The degree in statistics involves at least four years of full-time study and requires completion and discussion of a dissertation. The majority of the courses concern statistics and mathematics.

The degree in biology is a university course of five years and requires completion and discussion of a dissertation. Only one course of elementary statistics is part of this university course. Most of the pharmaceutical statisticians with such a degree also have a postgraduate degree in medical statistics. Four Italian universities offer this degree at the moment. The duration of the whole program of these postgraduate courses is three to four years.

A postgraduate degree of around three years duration, called 'dottorato,' is available for most disciplines, including statistics and biology. It is more oriented, however, towards a teaching career or theoretical research than to applied work. Only a few pharmaceutical statisticians have such a degree.

Most Italian universities offer so-called 'short-degrees,' which are university courses lasting generally two to three years. This degree is offered for statistics and around 20% of pharmaceutical statisticians have such a degree (included in the 50% reported above).

Responsibilities of a pharmaceutical statistician in Italy include active collaboration with physicians in the planning phase of the clinical trials, writing the statistical sections of the protocol, conducting statistical analyses, writing reports, and supporting the interpretation of the results. In most companies, the head of the statistics department signs the study protocol and the report.

The regulatory agency for marketing authorization of pharmaceutical products does not have a statistical unit. In Italy, there is no professional register for statisticians.

The Netherlands

Four pharmaceutical companies have their main European office in The Netherlands, employing 30–35 statisticians in total. In addition, some local organizations of international companies employ one or two statisticians. Organizations providing services to the pharmaceutical industry, such as CROs and university institutes, employ 10–20 statisticians. Thus, in total, around 50 statisticians work in or for the Dutch pharmaceutical industry. Most of these statisticians have 1–5 years experience, with a minority having more than 10 years of experience.

A statistician in the pharmaceutical industry is usually involved in the clinical development plan and responsible for statistical aspects of study protocols. The statistical analysis and the statistical parts of the report fall under the responsibility of the statistician, in some companies with formal sign-off. In some companies the statistician is also responsible for data management.

A typical pharmaceutical statistician in The Netherlands will have an MSc in mathematics, with specialization in statistics after the BSc. The official title is Doctorandus (Drs) or Ingenieur (Ir). About 10% of the statisticians have a PhD. The duration of study is a minimum of four years and includes a substantial statistical project in the final year. Some other courses, such as psychometrics or agricultural science (genetics/breeding), have a strong statistical/mathematical content. Epidemiologists form a large group in the applied medical/statistical world in The Netherlands. To date, it is not possible to graduate as a medical statistician at one of the Dutch universities.

The Dutch registration authorities employ an epidemiologist and a part-time (0.2) statistical consultant. There is no official professional status or certification scheme for statisticians in The Netherlands at present. An initiative was recently started, however, for registration of biostatisticians and preparations for setting up such a scheme are in progress.

Spain

In Spain there are around 20 statisticians employed in 16 companies, plus 21 employed in 10 CROs working mainly for the pharmaceutical industry. Almost all are affiliated with the "Asociacion de Biometria Clinica para la Investigacion Farmaceutica" (ABCif).

There is no 'typical' profile for a pharmaceutical industry statistician in Spain, except for a negative correlation between formal statistical qualification and experience, due to the recent introduction in Spain of the university degree in statistics. Almost everyone has a scientific university degree (requiring at least five years of study), such as MD, chemist, physicist, computer scientist, or pharmacist, plus postgraduate courses in statistics.

A three-year course, roughly equivalent to a bachelor degree ("Diplomados") started around 1990 in several universities in Spain. A further two-year program, similar to a master's degree ("Licenciados") started in 1995.

ABCif is in favor of accreditation and in early 1996 changed its constitution to allow for a category of accredited members, who would be required to have a university degree with at least one year (full-time equivalent) of statistics, plus five years of experience in applied statistics, of which at least two years must be in medical statistics. Up to now, seven ABCif members have achieved accredited status, although there are at least 10 more members who would fulfill the criteria. There are no statisticians employed in the regulatory agency in Spain.

Sweden

The two large Swedish-based pharmaceutical companies together employ about 80 statisticians in Sweden. All major international pharmaceutical companies have marketing companies in Sweden and some of these employ one or more statisticians. In addition, companies make extensive use of CRO or academic consultants for statistical advice.

Approximately 20 of the pharmaceutical industry statisticians have a PhD, but the majority have BSc or MSc degrees with 1.5–2 years of statistics in combination with mathematics and computer science. Only a few have formal training in medical statistics, either from newly established biostatistical programs, from courses abroad, or from isolated university biostatistics courses.

New recruits receive considerable on-the-job training under the supervision of senior statisticians. Even for recruits with a strong educational background, it takes a long time to become familiar with the industry environment and the specific statistical problems it presents. Initially, they undertake operational statistical work under supervision; tasks normally include randomization, sample size calculations, statistical programming and analysis, internal statistical reports, and so forth. When more experience has been gained, the statistician will be given full project responsibility for protocols, reports, drug development plans, contacts with regulatory authorities, coauthoring of publications, methods development, statistical analysis plans, and so forth.

There is no professional authorization or certification in operation in Sweden. The Föreningen för Medicinsk Statistik (Association of Medical Statistics) has recently considered a scheme for biostatisticians based on the "Chartered Statistician" concept in the United Kingdom. Preference has been expressed, however, for international (European) coordination of such an approach. The Swedish regulatory agency (Medical Product Agency) employs three statisticians (3).

Switzerland

About six pharmaceutical companies in Switzerland employ approximately 100 statisticians, of whom approximately 75% are working in the two largest Swiss companies. A few CROs, working partly or exclusively for the pharmaceutical industry, employ about 12 statisticians. Experience in medical and pharmaceutical statistics ranges from zero to over 20 years, about 50% having between one and six years of experience. The number of statisticians working in the Swiss pharmaceutical industry has more than doubled in the last 10 years.

About 60% of statisticians have an MSc or an equivalent diploma in statistics, mathematics, or a related area. About 40% of the statisticians have a PhD. At least 60% of the statisticians working in the pharmaceutical industry in Switzerland are not of Swiss nationality and received their degrees primarily in their home counties, primarily Germany, United Kingdom, and France.

A diploma in statistics (about equivalent to an MSc) is awarded by one university (Bern); the other six universities and the two Swiss Federal Institutes of Technology award degrees in mathematics with the possibility of specializing in statistics or econometrics. The University of Neuchâtel offers a postgraduate diploma course (lasting two years) in statistics for academics with a degree in natural sciences or mathematics. Shorter one-year courses (35 and 30 course days) are also offered by the Seminars for Statistics at the Swiss Federal Institutes of Technology in Zurich and Lausanne, respectively, and by the Institute for Mathematical Statistics and Actuarial Sciences, University of Bern (36 course days).

Most statisticians joining pharmaceutical companies in Switzerland before about 1985 and working in the area of clinical research and development did not have a formal degree in statistics. Their degree was usually in mathematics (with courses in probability theory and/or statistical theory), physics, psychology or natural sciences. The training was on the job and by means of courses offered by Swiss and European universities or statistical societies.

In the early days of statistics in the pharmaceutical industry, statisticians were primarily seen as professionals in a service function, who helped to analyze and document data from trials and experiments, but were at best only marginally involved in the planning stage. Thereafter, it was increasingly recognized that statisticians in the industry could and did contribute even more significantly by improving the planning and decision making process, chiefly by introducing, adapting, and developing the ideas and principles of 'design of experiments' to clinical development. Much of the experience necessary to fulfill these tasks is still gained by training on the job. Statisticians now participate routinely in the planning of clinical projects and contribute substantially to the design of clinical trials. They plan and take responsibility for the conduct of the statistical analysis and participate in interpreting and reporting the study results. Generally, the trial statistician is a named coauthor (together with the medical expert) and signatory of the trial protocol and trial reports. Senior statisticians also interact with the statistical units of health authorities in Europe and the United States. In summary, biostatisticians today are considered professionals who add value to clinical development along with their clinical colleagues.

There is no certification scheme for statisticians in Switzerland. The regulatory authority does not employ any statisticians, but makes use of the services of an external statistical consultant.

The United Kingdom

Pharmaceutical companies in the United Kingdom employ over 400 statisticians, with more than 200 employed in contract research organizations providing services to the industry. The total number employed has been growing at around 10–15% per year since the late 1970s.

At least 56 of the 70 universities in the United Kingdom now offer full-time or part-time BSc/BA degrees in statistics, or in a related subject with sufficient statistical content to be acceptable to the Royal Statistical Society (RSS) for Graduate Statistician status (see below). These courses involve three or four years of full-time study and most require the student to complete a substantial statistical project in the final year. Many courses include a further one-year full-time placement in industry or commerce. In addition to the statistical content (typically 50–70%), most courses include a broader mathematical education, together with computing, numerical analysis, operations research, and so forth. A very few courses offer modules of medical applications of statistics or human physiology.

Around 20 universities now offer an MSc in statistics. Four give specialist programs in medical statistics/biometrics with specific applications of relevance to the pharmaceutical industry, including bio-assay, clinical trials, demography, survival analysis, and so forth. In addition to taking appropriate courses, MSc candidates are expected to present a thesis.

New entrant statisticians to the pharmaceutical industry will normally have a degree in statistics, with many companies now requiring an MSc or other higher degree. After about five years of experience (ie, at the stage where they are qualified to apply for the status of Chartered Statistician of the RSS) they will expect promotion to senior statistician. At this stage, most companies will assign duties appropriate to that of "Trial Statistician" in the ICH E9 guidance, that is, taking responsibility for statistical contributions to clinical trial protocols and study reports.

The main route for professional accreditation in the United Kingdom is the Chartered Statistician scheme operated by the Royal Statistical Society (RSS). Most successful applicants for Chartered Statistician (CStat) have a BSc/MSc/PhD in statistics, or in another subject with around 1.5 years (full-time equivalent) of statistical content, plus five years of practical experience. An alternative route is through passing the examinations for the Graduate Diploma of the RSS, plus four years of experience. In exceptional cases, a candidate without formal statistical qualifications may be admitted: this would normally require at least 10 years of practical experience of applying statistics at a responsible level, plus publications or other significant contributions to statistics, for example, in consultancy. The status of Graduate Statistician is open to applicants who have the necessary academic qualifications, but who lack the practical experience.

The designation of Chartered and Graduate Statistician is open to those working in all areas of statistics. While not constituting a formal accreditation scheme, ordinary membership of Statisticians in the Pharmaceutical Industry (PSI) is specific to the pharmaceutical industry. Ordinary membership is open to applicants who have a recognized statistical qualification equivalent to that required for the RSS Graduate Statistician and who are employed as statisticians in the pharmaceutical industry, which (since 1997) is taken to include contract research organizations. Around one third of the United Kingdom-resident ordinary members of PSI are Chartered Statisticians.

The United Kingdom regulatory authority (the Medicines Control Agency) employs three statisticians (2), two of whom have extensive experience within the pharmaceutical industry.