EFSPI
European Federation of Statisticians in the Pharmaceutical Industry
Representing Statistical Associations in Europe

Roles and career paths for statisticians in today's Pharmaceutical Industry

After the EFSPI European statistics leadership meeting 2010, EFSPI sent out two brief surveys to 19 pharmaceutical companies to assess the status of roles and career paths of statisticians in pharmaceutical industry. This report summarizes the status of statisticians in pharmaceutical industry based to a large extent on these two surveys.

1. Introduction

Two surveys were sent out October 2010 and July 2011 primarily to companies participating in the 2010 EFSPI leadership meeting. The questionnaire went out to 19 companies and responses were received by 9 companies, therefore results cannot be representative for overall pharmaceutical industry but may reflect the situation at least in a number of major companies. The survey was restricted to European pharmaceutical industry as developing a European viewpoint on the current situation seems quite important. Finally the situation in small companies and in CROs in Europe may be somewhat different and those differences are not covered by the questionnaire.

The questionnaire asked for information on roles, responsibilities, career paths for biostatisticians and examples of good strategic careers made as well as on some further information on the changing pharmaceutical environment. Feedback was obtained from a number of major drug companies with strong European presence, Abbott, Amgen, Astellas, Astra Zeneca, Bayer, GSK, Hoffmann-La Roche, Novartis and Orion.

2. Roles of statisticians in different companies

Statistical activities are in principle similar across the various companies who participated in the survey, see Table 1.

Table 1: Results EFSPI questionnaire: Biostatistics responsibilities in pharmaceutical industry

Area:		% (N=8)
Pre-clinical studies		63%
Pre-clinical safety assessments		63%
Modeling and Simulation		50%
Clinical studies		100%
Drug safety		75%
Biomarker		75%
Epidemiology		75%
Benefit-risk assessment		75%
Marketing studies		75%
Pricing/economics		25%
Statistical methodology		50%
Port-folio management		13%

N = number of companies completing the survey

Biostatisticians are involved in strategic, methodological and operational activities within clinical development and are well linked with other functions in this area, especially in clinical development, see Table 2.

The survey also supports our experience that meanwhile other tasks are sometimes taken on by statisticians, reaching from supporting pre-clinical studies to marketing trials, supporting candidate selection for entry into human and contributing to late stage portfolio management, see Table 1. Statisticians are working in epidemiology to define prevalence of certain diseases either to help define the right populations for clinical development or to help supporting evaluation of certain side effects of drugs during pharmacovigilance. In some companies there are methodological groups working on the development and application of new methods in clinical trials. Some statisticians became experts in biomarker analyses and how to handle high dimensional data like genetic data. Statisticians are also involved in modeling and simulation activities together with experts from other fields utilising model-based development strategies

and using mechanistic assumptions for the mode of action. Finally some statisticians work as well in different departments like drug safety to fulfill the needs of statistical support in those areas. This could involve activities using both clinical and preclinical drug safety.

Table 2: Results EFSPI questionnaire: Strategic contributions and impact of statisticians in pharmaceutical industry

Cross functional leadership responsibilities	(N=8)
Companies with cross functional leadership roles for statisticians	50%
Companies with less than three statisticians taking this role	25%
Companies with three to ten statisticians taking this role	25%
Involvement of statisticians in cross functional teams	(N=8)
Study management teams	100%
Member of pre-clinical teams	63%
Member of clinical teams	75%
Member of project teams	88%
Member of internal advisory boards	88%
Involvement of statisticians in decision making	(N=8)
Candidate selection pre-clinical	50%
Protocol planning	100%
Planning of development program	88%
End of phase II decisions	75%
Filing decisions	75%
Portfolio decisions	50%

N = number of companies completing the survey

Statisticians are also seen as strategic partners in clinical drug development. They are members of various project groups at various levels and in most companies their impact on strategic decisions in a project and beyond projects is usually recognized by other functions, see Table 2. For example, at the highest level, some statisticians sit on cross-functional development review boards advising on key decision-making, other's chair or participate in cross-functional protocol review committees, and others chair or participate in cross-functional product level or study level management teams.

3. Career paths

Career paths available at different companies vary in terms of the organizational structure and naming of roles from which potential posts become available, but the actual roles that statisticians fulfill have many items in common. As expected, all companies have a managerial career path, but this career path alone is not appropriate for all statisticians, and this career path won't be available to all statisticians at any one time. In all companies responding there is also a career path possible allowing statisticians to become more senior drug development partners in various levels of projects. Beside this some companies have also a more technical or methodological career path however this is not uniformly implemented in all companies.

In basically all companies, statisticians in clinical development usually start as a study statistician on a smaller study or supporting a study statistician on a larger or more complex study. The first advance would then consist typically in getting ready for taking over a complex study and as a further step being the lead statistician for a whole program. When having reached such a level, statisticians can go on and become a manager for a group of statisticians or a number of programs, typically either for a site or for a therapeutic area. But in most companies, statisticians can also stay on a cross functional path and continue in taking more leadership roles within a project but then cross functional. This could be to lead an early development team, a late development team, to lead the team delivering a filing or leading even broader cross functional teams. Such careers still seems rather infrequent, but examples have been provided for a small number of companies.

In some companies developing further in a methodological direction could also be a possibility. Such career developments have included specialization for certain areas and becoming a methodological expert therein or at the end moving again into a management function for such a group. There could be a lot of recognition inside and outside of the company connected with such a position, even when not combined with managerial responsibilities. Frequently, a special job title is used and reflects and awards such expertise and the corresponding value it brings to drug development.

A part of the survey was also a review of available job titles. The main objective for this was primarily an expectation that job titles could reflect some of the career path possibilities. Furthermore, it has been insightful to see as well how title structures are connected with job titles. Job titles are as expected different between different companies although similarities can be observed. There is however one trend obvious in most companies concerning the wording of more senior titles in which companies move away from "statisticians" to "statistical scientists" reflecting an inherent growth of many statisticians into drug development.

Examples of career paths: a retrospective view

One element in the survey was to ask for examples of successful career paths of individual statisticians, especially when going beyond managerial careers within biostatistics or biometrics departments. Such successful careers of statisticians in industry could provide more insights beyond the obvious careers for individuals and inspire them to recognize that broader opportunities are possible. Such paths can also lay out what is possible and serve as the foundation of goals for statisticians in the industry. Of course it has to be anticipated that predefined career paths for such individuals did not exist, nevertheless such paths already today reflect what is possible and what value statisticians can bring to a pharmaceutical organization.

Career examples as of interest here cover in principle two different streams, career paths moving along the managerial career ladder but crossing once the line to other functions and career paths focusing on taking leadership functions in cross-functional teams beyond statistics or biometrics.

Examples of managerial career paths:

- A statistician became head of statistics in the USA, then moved on to become global head of biostatistics and data management with world-wide responsibilities. Finally the person moved on to the IT department and took a senior company position there before becoming senior vice president in IT.
- A statistician became head of the statistics department. After some time this person moved to lead biostatistics, data management and epidemiology. Finally, the person became head of the drug safety department.

Examples of cross-functional careers:

- A statistician with some years of experience became statistics team leader of a larger project. Being successful in this role the person then moved on to be a therapeutic area leader for statistics. Thereafter, the statistician became a leader of strategic projects and finally global project leader for an important new treatment, i.e. one of the top cross-functional leadership positions in development.
- Another statistician worked as a study statistician and subsequently as a project statistician for a large project. Then this person moved on the managerial career path and became a biostatistics group leader. After some time the individual moved back into a cross functional position and became clinical team leader, a leadership position for all clinical activities in the development of a new treatment. Finally, this person successfully assumed the position of a global program leader.
- A third statistician started as a statistician in clinical development. This person moved on and became a project statistician for a large project. Taking on a leadership role as a submission leader was the next step in his career and also the first time this person took on cross functional responsibilities. Today, this statistician works as a clinical team leader with large cross-functional responsibilities.

There are some common features in all these different career paths. All statisticians basically started as study statisticians and gained there the necessary experience. But then they moved on and took more responsibilities within projects on the statistical side before moving on to further leadership positions. Irrespective of whether they went up the managerial path within the statistics department or not, at one point they crossed the line of the biometrics department and took on broader responsibilities in drug development, either cross functional or in other departments. It seems natural to believe that this was all due to a unique skill set of these people but it seems also natural that it could have been related to their work done before and to their knowledge they gathered specifically as statisticians in drug development. Making such career paths more widely known may support the statistical community in moving forward to see such career paths more frequent in future than today.

In many companies there is a rising demand for statistical help outside standard clinical trials. Simultaneously there is an increasing amount of various attempts of many companies to work on

their cost structure and by that to outsource less strategic tasks to more cost effective CROs or external partners. Table 3 shows how the current situation is evaluated in different companies. There are certain classical and well established activities that statisticians today perform on a daily basis which could fall under operational tasks which are a prime target for outsourcing. It is certainly wise for statistics as a whole to support such a strategy, and try to shape its content. It will be however also important to assess in the future the cost-effectiveness and strengths and weaknesses of these outsourcing strategies compared to retaining the statistical operational tasks in-house. There are a number of logistical issues to clarify for such outsourcing strategies, which primarily concerns communication flow and the additional overhead activities in terms of overseeing the outsourcing activities. Certainly at this stage, no one can yet determine how well such outsourcing strategies will work out at the end, but clearly some companies have decided to endorse this approach.

Table 3: Expected changes for biostatisticians

Changes in the environment	%
Plans to differentiate between operational and strategic activities for statisticians	50%
Plans to outsource statistics activities more than in the past to	
CROs	75%
Other sites being with better cost structure	63%
Increase in strategic tasks requiring more strategic thinking	75%
All statisticians are prepared for the environmental change in pharmaceutical industry?	0%
All statisticians appreciate a shift to more strategic work?	0%
How many of the statisticians would not appreciate a shift?	
Less than 10%	25%
10 to 25%	50%
More than 25%	25%

As a consequence of such outsourcing strategies, more statistical resources may become available within companies, and these resources can be focused and used for more important activities that require internal statistical expertise. Companies are seeking today not only outsourcing strategies but also other strategies or processes which could speed up drug development or reduce costs. Some examples include applying new thinking, new methods and/or new study designs like

adaptive designs. In addition, Health Authorities are also challenging industry to think about new ways of doing drug development. Here however there is more interest on improving the quality and usability of data submitted to allow better safety evaluations or better benefit-risk assessments for instance. In almost all of such new initiatives statisticians play or will have to play a central role to make them successful. Apart from this it is a stimulating environment for statisticians and offers the statistical community new fields in which statisticians can take on responsibilities and show their value to the industry. Such new fields have been already showing up today in individual companies, but may do so in the future across the whole industry.

4. Leadership roles in a cross-functional matrix structure

The environment in which statisticians operate today, specifically in clinical development, is built on cross-functional teams in basically the whole pharmaceutical industry. Such cross-functional teams may operate on a study level covering all activities necessary to conduct successfully one study. They may operate on a development level to ensure the right development program to get a new molecule approved by health authorities and finally onto the market. And they may operate on a project level in which all different activities around one molecule come together, pre-clinical and toxicology activities, formulation and manufacturing, clinical development and marketing. In all companies, statisticians have a place on these cross-functional teams, perhaps with some controversy on participation in teams on highest project level. As laid out above it is for the future of statistics very important how statisticians operate in such cross-functional teams.

4.1 Importance of cross functional teams

For successful work in a matrix structure, statisticians require different skills compared to those learned at university. Good team working and communication skills may be at least as important as methodological knowledge on the best statistical method or study design to be used. Statisticians need to learn the language of their partners; falling back into a more technical mathematical language may be seen as safe harbor but is almost always a clear sign of not reaching out to their partners successfully and not being heard. It has to be stressed that the value of statisticians for the pharmaceutical industry is not in having said or proposed the right thing but in being heard and having ensured that the right things are implemented. As a consequence,

statisticians on such cross-functional teams need to be ready to take on leadership roles in order to function successfully.

Such leadership roles however do not come by themselves. The environment is largely driven by the medical community, at least on study and development level, and formal leadership roles are not evident for statisticians. In many ways, statisticians today need to act in leadership roles without formal authority. This is certainly one of the major challenges for successful statisticians in pharmaceutical industry and a lot of the success of the statistical community depend today and probably even more in future on successful work in this area, not only for personal career development, but also for how valuable statisticians will be seen in industry and how much industry will open further working fields for statisticians as discussed in section 3.

A successful work of statisticians in such cross-functional teams is very much depending on a mind shift change for statisticians. Successful statisticians see themselves more as drug developers with statistical background than statisticians with some experience in drug development. Statisticians are usually not prepared for such a mind shift by the educational system they are coming through and many hamper with this development step. The result of this is that they tend to remain too technically orientated, not seeing all constrains and not all priorities and – probably most important – being rather seen as consultants than as core members of teams with the consequence that they may be frequently not heard. Therefore, an essential question for the statistical community in pharmaceutical industry is how to support statistical staff in making such changes in their mind shift and by that to support integration of statisticians in such cross functional teams.

4.2 How to support statisticians in cross functional teams?

There are a number of important questions we need to ask ourselves:

- Do we need to do more to encourage development in matrix roles or cross-functional roles?
- Is the culture right or do we need to challenge the established model?
- What expectations are there from our colleagues in other disciplines -- do they see statisticians as leaders rather than operational technicians with more limited leadership potential?

- How can we support statistical staff in managing these challenges well?

A number of things indeed exist what we can do as a statistical community to support statistical staff to get onto leading roles with such cross-functional teams successfully, in informal or formal leading positions.

- There is a need to make the mind shift more explicit. Statisticians taking on responsibilities in cross functional teams need to be evaluated not only by their statistical methodological capabilities but also on their leadership capabilities and by how much they are willing and able to get into a drug developers role. Incentives and awards need to be largely driven by success in these areas.
- It has also to be made clear that success in cross-functional teams is most important for the success of statisticians in pharmaceutical industry and that career paths taking place on such cross-functional teams are viewed as equally important and rewarding as career paths within statistics management. Such career paths need to be clearly laid out such that the direction we need largely to drive for is clear to every statistician.
- More support of statistical staff in terms of training courses is required for how to operate in cross-functional teams, how to successfully negotiate, and on how to lead without formal authority.

It is a responsibility of statistical organizations like EFSPI to support statisticians in industry in this task. It is interesting that today statistical communities primarily concentrate on methodological training, on technical solutions and on development and acceptance of new methods by health authorities. Without saying this should also remain a major focus of such statistical communities in the future, but there is certainly an element of what statistical communities could do more and better to support also the integration of statistics in drug development:

- Statistical communities could put more weight on skills required for cross-functional work in their meetings by having sessions focusing specifically on skills required for good performance within matrix structure etc.
- Statistical communities should not only focus on statistical training but also on training which helps statisticians to improve in their ability to talk the language of their partners,

focusing on drug development problems which are not necessarily only of statistical nature etc. We need to change the perception statisticians have of their role, from being a statistician working in pharmaceutical industry to a drug developer with statistical expertise.

- Statistical communities could offer special training courses on how to act within matrix structures, leading as a statistician without formal authority etc.

4.3 What can we improve within companies?

A lot of the work obviously has to be done within a sponsor company, especially with regard to career paths for statisticians, for training and on how to generate a good development environment for statisticians to show best their value. A number of questions we need to ask ourselves:

- What kind of internal training is required?
- What kind of career paths should be laid out?
- How could an ideal career path map for statisticians in pharmaceutical industry look like?
- How can we support an environment within a development organization to support such activities?

Specific internal training programs can be designed to focus on negotiation skills, teamwork, how to lead without formal authority and how to increase drug development knowledge of our staff. An aspiration could be to strive for an environment in which career paths cross-functionally is also open for statisticians and citing examples from within and outside the company may be helpful in this regard. Finally, we can generate general career paths which stress the importance of cross functional work and will reward statisticians the same way when making their career cross-functionally in contrast to statisticians going for a managerial career. The help of cross statistical communities like EFSPI and others are largely needed to achieve such changes.

5. Conclusions

We have attempted to record the range of job roles statisticians typically take in pharmaceutical industry today, what range of tasks they are typically involved with and where their value is today for drug companies. Job roles are connected with titles and career possibilities. In general there is still a move going on in industry to expand the strategic value of statisticians.

The next decade, however, will pose some challenges for the pharmaceutical industry in general and these challenges will lead to an adaptation of processes that will impact statisticians. It is, however, in the hands of the statisticians themselves to determine how they will manage their future. Some job roles might become obsolete during this process, others may be moved out of Europe. It nevertheless looks at least today like many opportunities will remain and new opportunities will come up for statisticians to demonstrate their value. Times of change may actually be good times for statisticians to be in as – given that new solutions are required for old questions – statisticians can really use their knowledge and add substantially to define new paradigms for the next decade. As said it may be to a large extent to the statisticians themselves to shape their future. If doing this well, there is no doubt that the future will remain quite promising for statisticians in pharmaceutical industry.

We look to EFSPI and the national member associations to help shape the future of the statistical community in the pharmaceutical industry. We encourage individual statisticians to aspire to be successful in the changing R&D environment, by seeking opportunities to expand their skills sets in other non-traditional areas and by feeling motivated and excited by newer areas of statistical application. By all this, the statistical community will pro-actively engage in shaping its future and embrace new opportunities that will come as the pharmaceutical R&D model evolves.

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