

Future roles and opportunities for statisticians in pharmaceutical industry

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Abstract:

The Pharmaceutical industry is undergoing significant transformation with the development of new treatments becoming increasingly complex and expensive. This changing environment provides statisticians working within the pharmaceutical industry with uncertainties but also with opportunities to shape their future and influence the changes being made. Outsourcing to Contract Research Organizations (CROs) and/or lower cost sites within the company may be perceived to be a threat for statisticians working in big pharmaceutical companies where the environment is more and more cost driven. On the other hand, the increasing importance of more strategic statistical responsibilities brings opportunities for the statistical community in the pharmaceutical industry. These opportunities however may change the skill set of statisticians required in the future and at least some statisticians will need support to adapt to the new environment. It will be important for statisticians to pro-actively engage in shaping the future and embrace new opportunities that will come as the pharmaceutical model evolves. Statistical communities and universities should also take these changes up in the way they provide training to statisticians working in the pharmaceutical industry.

Key words:

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1. Introduction

The pharmaceutical industry is undergoing significant transformation since the second decade of the 21st century (Andrew J., 2012). The development of new treatments is becoming increasingly complex and costly given the successes in the past decades. Investments to address the key requirements from regulatory and payer agencies around the world are rising and the cost pressure from national health care budgets is increasing. Since the beginning of this decade the industry is seeking new concepts and approaches for developing medicines, many of which are focused on leveraging scientific innovation and advances in technology in parallel with significant cost containment measures.

This continuously changing environment provides statisticians working within the pharmaceutical industry with opportunities (Chuang-Stein C. et al, 2010, Liss C.L. 2003) but also brings uncertainties. Some statisticians could perceive these changes as threats. Almost all pharmaceutical companies are reviewing and implementing significant changes in their R&D strategies aligned with redistribution of internal focus from contextual capabilities (necessary but no longer perceived to be core internal capabilities) towards core capabilities (internal expertise or operations perceived to create value differentiation), see also Moore G.A., 2008. Most companies have moved away from the old 'block-buster' R&D model in which a few but financially very successful products would best suit the portfolio to one with more diversification and strategically managing a larger portfolio of smaller products. The newer models are more focused on patient-directed health outcomes which bring new dimensions to data collection, analysis and reporting. On the whole, the pharmaceutical statistics community has had limited success in articulating its value proposition as it specifically relates to being a full strategic partner across the spectrum of drug development. As with many other disciplines, statistical tasks may be classified as strategic or transactional, the latter frequently referred to as operational tasks. Strategic tasks could be defined as those who really impact the design, the results and the way the results could be used economically, either on study or on program/compound level and may go beyond pure statistics. This reaches from design of development programs, study design, result interpretation and beyond. Operational tasks on the contrary deal rather with the implementation of designs. This could be protocol, analysis plan and report writing as well as programming or quality control. In the interest of reducing costs operational tasks are subject to an increasing degree of outsourcing to external partners like Contract Research Organizations (CROs). It will be very important for the statistical community in the pharmaceutical industry to deal with this changing environment (Grieve A.P., 2002), understanding the new opportunities it brings and proactively managing the potential risks. Statistics have a lot of different partner functions in the development environment and also these partner functions are impacted to different degrees by these changes. Data management and programming for example are certainly heavily impacted by the trend for outsourcing while other functions like regulatory or clinical science are less affected due to their strategic scope.

A statistical leadership forum organized by the European Federation of Statisticians in the Pharmaceutical Industry (EFSPI) has set up an initiative to actively support and influence such a process. A survey among European based companies and a series of meetings took place and results were published (Burger H.U. et al, 2012). This EFSPI initiative looked into the different roles statisticians take on and what kind of career paths is available for statisticians in the pharmaceutical industry today (Liss C.L., 2003). The survey focusing on statisticians working in pharmaceutical industry largely excluding CROs basically confirmed that the major focus of statisticians is still on clinical trials with some diversification taking place into other areas like preclinical research and marketing/pricing. We can see however that the role of statisticians is also expanding into other areas like drug safety and benefit risk assessment up to portfolio management. Career opportunities are broader today with cross-functional leadership opportunities in half of the companies. Statisticians today take on more responsibilities and leadership positions. Finally, basically all companies participating in the survey anticipated changes with more operational work going to low cost sites either within the company or to CROs whilst internal work at main sites becoming more strategic. The majority of statisticians seem to be fit for such change, however, 10 to 25% of staff approximately will struggle with it (Burger H.U. et al, 2012).

In this position paper, we summarize what will be important for statisticians to manage the future. We highlight some areas in which statistical communities could help statisticians to manage this period of change. The paper is by in large focused on the situation of statisticians working in pharmaceutical companies with R&D capabilities. However, some of the aspects will also be relevant and important for statisticians working in companies that support the pharmaceutical industry and perhaps for statisticians working in academia or academic trial institutions.

2. Evolving and future roles and opportunities for statisticians

Biostatistics is an established function in clinical development today and an integral part in how companies run studies today. Most of the statisticians employed in the pharmaceutical industry work in this area. Over the years the strategic importance of biostatistics in the development of new drugs has increased. Before the 1970s, statisticians in the pharmaceutical industry worked in biology, toxicology and other areas of research, moving into clinical research in the 1970s and 1980s due to changes in the regulatory environment. Initially the statistical engagement focused on a consulting role but then quickly adapted to taking more responsibilities in clinical studies and later on the statistician became an essential player in designing clinical studies and clinical development programs. This was only possible by partly moving out of a narrowly defined statistical area of clinical trials to a broader and more strategic view on the role statisticians can play within the drug development process.

Nevertheless, today's work of statisticians in this area can be seen as a mixture of strategic and operational work. A large number of statisticians today deal with operational tasks like analysis plan writing,

documentation, programming or validation of programming and report writing. The amount of strategic work has increased, for example in designing clinical development plans involving several protocols' designs, interpretation of data and collaborating in decision making. Some statisticians have reached higher levels of strategic influence in their respective companies and are highly recognized partners in decision making and regulatory engagement. The differentiation between strategic and operational tasks is however not clear cut: As a word of caution it has to be noted that even in apparently more operational roles a lot of business critical strategic aspects arise and therefore a separation in operational and strategic statistical tasks for statisticians may be overly simplified and potentially misunderstood. For example, planning new studies now requires much more clinical trial simulation than in the past, and when these studies are analyzed and reported, the interpretation of study results will require appropriate statistical expertise.

It will be important for statisticians working in clinical research to increase their strategic impact on planning and most importantly on interpretation and decision making of clinical trials. More operational activities will be subject to outsourcing. It will be important to make sure that all activities have important strategic components and statisticians focus on these. This demands a further growth of statistics into drug development where statisticians regard themselves more as developers of new drugs with a statistical background than statisticians just working in this field. This is a change in the mindset away from what is statistical interesting to what is really needed in a drug development program. This change is certainly true for statisticians working in the pharmaceutical industry but more and more also for those working for a CRO.

Additionally, it is important for statisticians to think beyond clinical development and to understand the broad scope in which statisticians in the pharmaceutical industry operate. The majority of statisticians work in clinical development with many possible career paths, but it is also important to understand that there are other areas in which statistical expertise is needed, either already today or in the future. In many companies there is a rising demand for statistical help outside standard clinical trials. Simultaneously there is an increasing amount of attempts of companies to work on their cost structure and by that to outsource less strategic tasks to more cost effective CROs or other external partners. It will be an important step for statisticians to play key roles integrating the strategic elements with the diverse sourcing strategies for more transactional tasks. It is certainly wise for statisticians to support cost effective strategies where they make sense and play a role in shaping its content. As a consequence more statistical resources may become available within companies, and it will be important to see if such resources could be redirected to other statistical demands emerging within the company.

Cost effective strategies will of course not be the only course for companies to reshape their business model. Innovation may be at least equally important and innovation may concern many different areas, some of which will require additional statistical support. Some examples include applying new thinking, new methods and/or new study designs like adaptive designs or a refocus away from individual study designs to whole development

programs. In addition, Health Authorities are also challenging the industry to think about new ways of conducting drug development. Here however there is more interest in improving the quality and usability of data submitted to allow better benefit-risk assessments for instance. In these new initiatives statisticians play or will need to play a central role to make them successful. It is now more than ever before a stimulating environment for statisticians where the statistical community can embrace new fields with new responsibilities. Such new fields have been already established in some companies, but may do so in the future across the whole industry.

There are a number of areas in which statisticians may work already today or will work in future:

- Disease modeling
- Non-clinical statistics
- Biomarker development
- Drug safety
- Epidemiology
- Benefit risk assessments
- Market access, health economics, and outcomes research
- Portfolio management
- Pharmacovigilance and data transparency
- Devices and Diagnostics
- New Technologies

In addition, data sharing initiatives were recently started, first by EMA followed by a number of company initiatives. In the future, large study datasets from industry will also be available outside companies. This is an important step forward potentially leading to an optimized use of study information long term (Fletcher C. et al, 2013). The consequences of this development for statisticians working in the pharmaceutical industry as well as in academia is however not yet clear today and can lead to further changes in the statistics work environment.

Statistics organizations within companies as well as individual statisticians are recommended to keep a close eye on all these areas to seize opportunities when they arise. However, we still need to note that the skill set for statisticians required for being successful in any of these new areas could be different from the one in clinical development and even the skill set required from a successful statistician in clinical development in the future is shifting from operational skills to technical and strategic skills. Not all statisticians, however, may be willing or prepared for such a change (Burger H.U. et al, 2012). At least a part of the statisticians will need help and the question arises how to best support them in this change.

3. Impact for statisticians

Such a shift in the work field as described above will also require a shift in the mind set of many statisticians in the pharmaceutical industry. In order to be successful statisticians need to show their willingness to move away from more operational areas of work they know very well and in which they have obtained a high degree of expertise, to new more strategic areas in which they would need to further develop their expertise. There will be an increased need to apply more strategic skills, for example in the planning by assessing the risk of a study or a whole program, up to the interpretation of study results in the light of the clinical development pathway. More technical skills, for example to deliver certain analyses or simulations in a timely fashion, are needed. Statisticians also need to change the way they see themselves contributing to the pharmaceutical industry, moving away from being statistical experts delivering on key operational tasks to being drug developer experts with a statistical background providing strategic insights. They need to focus on the main issues in a development program which may only be partly of statistical nature. Statisticians who have been writing protocols and analysis plans in the past and analysed study data together with programmers and who achieved high qualifications in these domains may feel uncomfortable now moving out of this and start thinking about the choice of endpoints, the number of studies required and additional design considerations such as control groups and design options to more quickly come to decision points to stop or continue development such as adaptive designs. How can companies help in supporting such statisticians?

Changing career paths: New career paths should be created, some of them within biostatistics departments, some of them - and in the future more and more – outside biostatistics. Career paths taking place on cross-functional teams should be viewed as equally important and rewarding as career paths within a statistics function. Career paths should reflect different alternatives for statisticians to be successful in both technical and managerial roles. Rewards and incentives should be changed accordingly. This move is already ongoing today and can be observed in many companies (Burger H.U. et al, 2012).

Supporting an entrepreneurial mindset: In clinical development teams statisticians have today an established place. In other areas as described above their role is not yet that well defined and a more entrepreneurial mindset is required when working in such a field. A culture that challenges the established model should be supported. Statistical communities and the pharmaceutical industry need statisticians to be able and willing to cross functional and departmental lines. But even in established areas, statisticians can be active and seek out opportunities to provide more strategic impact.

Supporting team work and communication: Success in cross-functional teams is important for the success of statisticians in pharmaceutical industry. Being able to succeed and navigate in a matrix environment requires statisticians to develop additional skills compared to those learned at university. Strong team work and communication skills are as important as methodological knowledge on the best statistical method or study

design to be used. Statisticians need to learn to converse in the language of their partners; falling back into a more technical or mathematical language may be seen as safe harbor to statisticians, but for other functional collaborators it is almost a sign of failure and not being heard. The value of statisticians for the pharmaceutical industry is not only to think through methodologically sound approaches but also to be able to convince team members of their value to the project. Therefore, more encouragement is needed in developing statisticians in matrix roles or cross-functional roles and adequate training has to be in place.

Supporting leadership: 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.

Supporting openness and self-awareness: The earlier statisticians understand the demands of the changing environment, the more time they have to focus on adapting and seeking new opportunities. Being able to achieve this requires clear communication in the statistical community of how demands are expected to change, and a sense of ownership and agreement that this change is happening. However future developments cannot be predicted with certainty, therefore being able to manage change with some level of uncertainty is necessary. Statisticians need to have good self-awareness of their own abilities to manage change, and seek support where this is needed.

We believe it is also the responsibility of the statistical communities like IBS, and ISCB, statistical organizations like EFSPi and PSI, and training programs and course curricular at universities to support such a shift for the future. These bodies can provide support and advise companies and individuals who struggle to manage and accept such changes, for example through a statistical leaders forum, and help individuals to be successful in this new business environment. It is interesting that today academic training and 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 and education at universities should maintain the rigor in methodology. But there is certainly an element of training, universities and statistical communities could do more and which would better support the integration of statistics in drug development. For example:

- Increased emphasis on the skills required for cross-functional work by organizing sessions or training courses focusing on how to be successful within a matrix structure etc.
- Increased training opportunities for 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.

- Information on the changing environment to allow adequate self-assessment by statisticians of their skills and areas of development.

4. Summary and conclusions

The next decade will pose many challenges to the pharmaceutical industry and these challenges will impact statisticians. It nevertheless looks at least today like many opportunities will remain and new opportunities will come to light 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.

Statisticians will not only become more strategic in the future they will take on more cross functional leadership roles, and the areas in which they work will change. There are a number of domains where statisticians will get more involved in the future. All these domains require more specialized statistical expertise and strategic thinking. It will be one of the essential steps for the statistical community to seize such opportunities and take them on when they arise. Being open to change and agree to it where needed combined with the openness to look for other opportunities is the best strategy to move forward.

We look to statistical associations like EFSPI and the national member associations, statistical communities like IBS and ISCB, and academic institutions 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 model evolves.

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