

UNIVERSITATEA DE MEDICINĂ ȘI FARMACIE

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ȘCOALA DOCTORALĂ

DOMENIUL FARMACIE

**Biostatistical methods applied in
pharmaceutical research**

REZUMATUL TEZEI DE ABILITARE

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ABSTRACT

In habilitation thesis entitled “Biostatistical methods applied in pharmaceutical research” is structured in three sections. First section describes the personal, professional and academic achievements, the second section presents in detail the main scientific research after defending PhD thesis and the last section presents the future plans regarding the evolution and development of the professional, scientific and academic profiles.

In first section, *Professional and Academic Achievements*, I presented the entire academic and professional career during 21 years of activity in university environment. During this period, I passed the exams for obtaining the academic titles and for the leadership positions. In 2008, I defended the PhD thesis in the field of Mathematics, department of Mathematical Statistics within the Faculty of Mathematics, Bucharest University. Professional training has been one of my concerns with a multidisciplinary educational path, so I obtained a master’s degree in applied Statistics and Optimizations, Faculty of Mathematics, University of Bucharest. The last six years, the most prolific years of research, belonged to the Applied Mathematics and Biostatistics department of the Faculty of Pharmacy, University of Medicine and Pharmacy “Carol Davila”, Bucharest.

Regarding the academic career is based, on the one hand, on the didactic experience acquired by teaching the courses and seminars of Probabilities and Statistics, Modeling and Simulation, Applied Mathematics within the specializations of mathematics, informatics or economics and, on the other hand, on the fruitful experience within the Faculty of Pharmacy in teaching Biostatistics and Applied Mathematics courses applied to pharmacy students and residents of Clinical Pharmacy and Pharmaceutical Laboratory. Starting with 2018, I started teaching the course and LP of Biostatistics and Bioinformatics within the Master of Nutrition and Food Safety organized by the University of Medicine and Pharmacy "Carol Davila". The statistical principles taught are used in pharmaceutical and nutritional research to plan and conduct analysis studies and to answer investigation questions. In recent years, together with colleagues in the discipline of Applied Mathematics and Biostatistics, efforts to update and improve teaching tools have been greatly streamlined, with particular care for the continuous improvement of the quality of performance results.

In the second section, entitled *Scientific Achievements*, I have detailed the main research directions sustained by the most important publications, as it follows:

➤ ***Multivariate Statistical Analysis in Pharmaceutical Process Research***

Multivariate statistical methods are a statistical procedure in which more than two variables are analyzed, which vary simultaneously in relation to each other, regardless of their nature. The first category of tests analyzes the dependence of variables and here we can mention the linear and logistic regression, the canonical correlation, the analysis of variance or the modeling of the structure equation. The second category of tests includes procedures aimed at the interdependence between variables and it is desired to discover the internal structures of the studied data. The tests referred to here are those of factor analysis, cluster analysis, correspondence analysis, or multidimensional scaling. Experimental pharmaceutical models are treated with extreme rigor by applying multivariate statistics, so the contribution to a better understanding of the dynamics of events is justified in most mandatory situations.

Although the statistical apparatus is endowed with sophisticated computational techniques, statistical programs calculate with very high accuracy and speed, it should be noted that the interpretation of results in the case of multivariate statistics is not easy. That is why, sometimes, research in interdisciplinary teams is essential and the debates in groups of experienced researchers give a full understanding of the investigated pharmaceutical processes. This research direction is sustained by ten ISI articles, two of which are published in Q1 area.

➤ ***Computational statistical techniques for small data***

The study of bootstrap techniques is extremely useful in the study of small samples, data extremely common in pharmaceutical research on animals. FDA regulations restrict, for ethical reasons, easy to understand, the number of individuals in animal research and therefore many classical statistical methods are difficult or impossible to apply.

We have highlighted the superiority of computerized methods for evaluating estimates provides valuable information on the adequacy of probabilistic models applied compared to classical ones. The bootstrap method is an extended computational approach to understanding empirical data and is based on resampling and statistical estimation. It is a powerful tool, especially when only a small set of data is used to predict the behavior of systems or processes.

In research on animal or nutraceutical studies, we applied this modern statistical method based on computational simulations to characterize and compare as efficiently as possible the data from clinical trials with few observations. The bootstrap technique is a statistical

method that does not depend on any hypothesis of data distribution and can be considered appropriate for estimating some essential parameters in the analysis of data through different types of bootstrap confidence intervals. This research direction materialized through 2 ISI Proceedings articles and 4 ISI articles, two of which are published in Q1 area and one in Q2 area.

➤ *Statistical Analysis of Epidemiologic Data*

Statistical methods are at the heart of most epidemiological and medical research. It allows us to identify risk factors for disease and effective drug treatments and to generalize accurately and confidently. In addition, while basic research leads to an understanding of the biological mechanisms by which exposure produces or prevents disease, only epidemiology allows quantification of the magnitude of the exposure / effect relationship, which only then clarify, in terms of the biological mechanism, fundamental statistical research.

All this research in identifying risk factors with optimistic results was the basis for trying to find new aspects related to the medical crisis caused by the new Covid-19 coronavirus or the impact of various other viral infections. I published 4 ISI articles, one of which is published in Q1 and, also, I participated with three articles in the conference, Nutrition, diet therapy & food safety in the context of the COVID-19, Bucharest, May 28-29, 2020.

The third section presents *Future plans regarding development of the academic, scientific and professional activities*. The academic activities combine teaching and scientific research to ensure a high-quality education. The permanent improvement of the didactic activities is focused on updating both the theoretic and practical activities on the field specific for the teaching subjects and encouraging the new generation to improve their skills by participating in the scientific research.

The scientific directions which are previously described with significant results will be considered for the future, but I will also take into account the development of related directions. The main objectives are to develop partnership in the priority areas for the design of innovative products and the development of new technologies within the research directions, to attract funding by future projects and to disseminate the results by publishing high impact scientific papers or by filing patents applications. Both the academic and scientific activities are correlated with the professional direction which will be focused on maintaining an active involvement in the socio-professional activities specific for the pharmaceutical community.