NEUROMETHODS

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Clinical Trials In Parkinson's Disease

Edited by

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Dedication

To my wife and children, whose endless support was essential for the completion of this book.

Preface to the Series

Experimental life sciences have two basic foundations: concepts and tools. The *Neuromethods* series focuses on the tools and techniques unique to the investigation of the nervous system and excitable cells. It will not, however, shortchange the concept side of things as care has been taken to integrate these tools within the context of the concepts and questions under investigation. In this way, the series is unique in that it not only collects protocols but also includes theoretical background information and critiques which led to the methods and their development. Thus it gives the reader a better understanding of the origin of the techniques and their potential future development. The *Neuromethods* publishing program strikes a balance between recent and exciting developments like those concerning new animal models of disease, imaging, in vivo methods, and more established techniques, including, for example, immunocytochemistry and electrophysiological technologies. New trainees in neurosciences still need a sound footing in these older methods in order to apply a critical approach to their results.

Under the guidance of its founders, Alan Boulton and Glen Baker, the *Neuromethods* series has been a success since its first volume published through Humana Press in 1985. The series continues to flourish through many changes over the years. It is now published under the umbrella of Springer Protocols. While methods involving brain research have changed a lot since the series started, the publishing environment and technology have changed even more radically. Neuromethods has the distinct layout and style of the Springer Protocols program, designed specifically for readability and ease of reference in a laboratory setting.

The careful application of methods is potentially the most important step in the process of scientific inquiry. In the past, new methodologies led the way in developing new disciplines in the biological and medical sciences. For example, Physiology emerged out of Anatomy in the nineteenth century by harnessing new methods based on the newly discovered phenomenon of electricity. Nowadays, the relationships between disciplines and methods are more complex. Methods are now widely shared between disciplines and research areas. New developments in electronic publishing make it possible for scientists that encounter new methods to quickly find sources of information electronically. The design of individual volumes and chapters in this series takes this new access technology into account. Springer Protocols makes it possible to download single protocols separately. In addition, Springer makes its print-on-demand technology available globally. A print copy can therefore be acquired quickly and for a competitive price anywhere in the world.

Saskatoon, SK, Canada ***Wolfgang Walz***

Preface

Parkinson's disease is the second most frequent neurodegenerative disorder after Alzheimer's disease. Parkinson's disease is considered by many authors as a pandemic. Indeed, the prevalence of this disease, and thus disability and deaths owing to it, more than doubled from 1990 to 2015. The Global Burden of Disease Study estimated that 6.2 million individuals had Parkinson's disease in 2018. The number of affected persons will likely reach 14.2 million in 2040.

Parkinson's disease seriously affects quality of life. Indeed, the disease has a profound and progressive impact on various neurological functions. Motor symptoms such as bradykinesia, rigidity, and tremor are the cardinal symptoms of the disease. Notwithstanding, quality of life is more affected by non-motor symptoms. Patients with Parkinson's disease are frequently affected by cognitive impairment, mood disorders, autonomic disturbances, troubled sleep, and sensory symptoms. Therefore, both motor and non-motor symptoms need to be treated in order to achieve satisfactory quality of life in patients with Parkinson's disease.

Randomized, controlled, double-blinded clinical trials are the cornerstone of the assessment of drugs and medical devices efficacy and safety. Randomization reduces the possibility of selection bias, by assigning trial participants to treatments groups on a random basis. Double blind permits effective allocation concealment and reduces the risk of performance, attrition, and detection bias. Respectively, these biases occur when there are systematic differences between groups in the care that is provided or in exposure to factors other than the interventions of interest, or in withdrawals from a study, or in how outcomes are determined.

This book reviews major clinical trials for motor and non-motor symptoms in Parkinson's disease and discusses their most important aspects, including study designs, sample selection, and outcome selection. Therefore, it aids clinicians and researchers to better interpret results from clinical trials in Parkinson's disease and to design their own high-quality trials.

Buenos Aires, Argentina *Santiago Perez-Lloret*

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