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Novel therapeutic approaches in multiple sclerosis: Neuroprotective and remyelinating agents, the future of clinical trials in MS?

Background: With the ever-growing competitive landscape in conducting Multiple Sclerosis (MS) clinical trials and the unmet needs for more robust effects on long term disability and disease progression, novel therapies targeting different MS clinical forms and acting beyond relapse outcomes, are needed.

Objective: By 2020, more than 19 compounds would have been put on the market, essentially, modifying the outcome of acute relapses in relapsing remitting forms of MS (RRMS). Clinical trials in primary and secondary progressive MS forms (PPMS and SPMS) remain less studied as compared to RRMS. The underlying mechanisms leading to neuronal loss and degeneration, as a consequence of the initial demyelinating process, are becoming more understood. Agents providing neuroprotection or promoting remyelination are a growing necessity and need to be the focus of future clinical trials.

Methods: Retrospective analysis of Quintiles MS performance on 40 trials, as well as, a review of 345 global clinical MS studies, available in the public domain, has shown that the main focus of clinical research remains RRMS.

Results: Over 40,000 RRMS patients are currently participating in global interventional clinical trials where ARR, remains the primary objective. In addition, approximately 8150 patients with progressive forms of MS are taking part in clinical research where effect on disability is studied as a primary outcome. When it comes to patients with CIS (Clinically Isolated Syndrome) and NMO (Neuromyelitis Optica) this number drops below 2500. The search on drugs in development reveals 25 investigational injectable compounds from phase 1 to phase 3b and another 15 investigational oral compounds, both currently developed, primarily, in RRMS. Only very few neuroprotective and remyelination therapeutic trials for MS are ongoing, 6 and 4 respectively. Furthermore, there are 8 stem cell trials being investigated as potential remyelinating agents.

Conclusions: The current MS clinical trials environment focuses mainly on developing drugs targeting the reduction of the ARR in RRMS patients in a consistently increasing competitive arena. Thus, it is becoming more and more challenging finding patients willing to participate in clinical research with so many therapies available to them and additional products scheduled to arrive on the global market in the near future. The analysis reveals that it is essential that more effort is deployed in developing agents in more progressive forms of MS and those that have more significant effect on disability outcomes. Although clinical trials with compounds developed as remyelinating agents remain limited for different scientific and methodological reasons, it is crucial that this area expands to meet an unmet need: Robust and positive effect on long term disability and disease progression in MS patients.

Biography

Marie Trad is an Executive Medical Director, acting currently as the Medical and Scientific Drug Development lead in Neurosciences within the CNS Therapeutic Delivery Unit at Quintiles. she is a board certified Neurologist and qualified Neuroradiologist from the Pierre and Marie Curie University of Paris, France. She has over 25 years of CNS experience of which 11 years as a clinical Neurologist/Neuroradiologist and 14 years of pharmaceutical industry, focusing on clinical trial management, providing medical, clinical and global strategic support related to Neurology and Psychiatry trials.

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