

## Defining reliable disability outcomes in progressive MS

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There are challenges involved in accurately measuring the gradual accumulation of disability in MS. This is one of the key hurdles facing clinical trials of new treatments for progressive MS, because a slow accumulation of disability can be difficult to accurately capture during the short time-frame of a standard clinical trial. This means that any improvements brought about by the treatments may also be difficult to capture.

Current clinical trials for progressive MS use a standard scale called the Expanded Disability Status Scale (EDSS) to measure the accumulation of disability and determine the effectiveness of new treatments to slow or halt this process. The scale ranges from 0 – 10 with higher scores being assigned to people with more severe disability. When measured across multiple time-points, an increase in EDSS score over time can be

used to predict the progression of the disease over the next 10 years.

Led by former [MS Research Australia Fellow](#) Dr Tomas Kalincik from the University of Melbourne, a group of scientists from around Australia have been evaluating the reliability of the [EDSS](#) for measuring clinical outcomes in MS research.

They looked at information from the international MSBase clinical database and analysed the EDSS scores from 16,636 people. Using data collected in the first 3 to 6 months after diagnosis, the researchers developed a statistical tool to predict a person's level of disability in five years' time. They then compared these predicted scores against each person's actual level of disability at five years.

The researchers found that the statistical predictions of disability progression tended to over-estimate the level of long term disability.

This may be because many people, in the first 3-6 months after diagnosis, are in an acute phase of illness prior to remission. The researchers found that many symptoms in the first 3 months are more likely to be temporary symptoms which regressed back to baseline, and were therefore not a good predictor of long term disability.

However, they found that measuring symptoms over a longer 12 to 24-month period, was a better gauge for identifying the persistent symptoms that are a better predictor of long term disability. The researchers recommend that extending the time over which initial disability progression is measured will enable researchers to improve the accuracy of the predictive model and establish better-quality predictions of irreversible disability in progressive MS.

Improvements in the way disability progression is measured in clinical trials is a key goal of the [International Progressive MS Alliance](#). As this study shows, we urgently need improved methods for using disability scales in clinical trials, such as increasing the length of time EDSS scores are measured or using different biological markers of progression or disability in clinical trial settings. This will lead to better treatment outcomes for people with progressive MS.



MS Research Australia is a managing member of the International Progressive MS Alliance which will award \$31 million over 6 years into new research into progressive MS.