

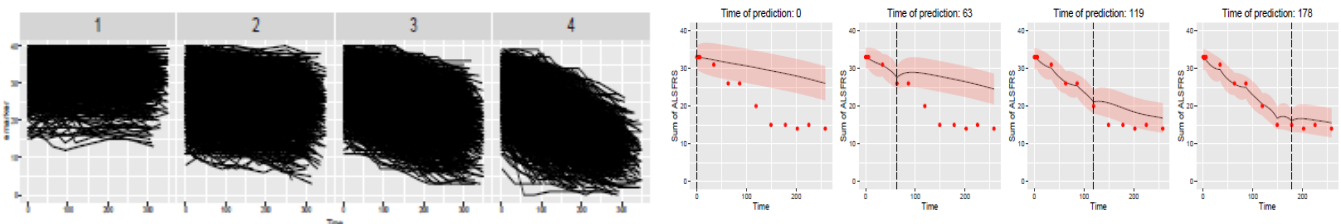
## Analysis, Prediction, Stratification, and Monitoring of ALS Disease Progression

### Background, Motivation, and Need

Clinical research and trials in amyotrophic lateral sclerosis (ALS) are complicated by the heterogeneity of the ALS population characterized by patient variability in the disease progression rate, site of symptoms at onset, and survivability. This heterogeneity also undermines personalized prediction of the disease progression rate and pattern. However, reliable personalized prediction could improve patient care and quality of life for patients and their caregivers, advance the ability to assess treatment influence in a clinical trial, and reduce the number of patients necessary in the trial to achieve statistically significant results.

### Contribution and Innovation

Using clinical data (lab test results, vital signs, etc.), we developed algorithms producing models that: 1) predict progression rate, progression pattern, and disease state; 2) identify factors (from lab test results and vital signs) that are essential for prediction, and their relations with the ALS disease state for different functionalities (e.g., walking, speaking, breathing); 3) demonstrate factor value combinations that relate to different disease severities (say mild and severe patients); 4) stratify the heterogeneous trajectories of disease progression into homogenous sub-groups, assign a new patient to a sub-group, and predict individually for this patient rate/pattern/state; and 5) improve disease state prediction as data from additional clinic visits are added.



Stratification by trajectory to four patient groups

Real-time prediction that is improved with prediction time

### Product and Its Potential Market

A system that can be implemented on a personal computer or as an Android-based cellular application that demonstrates our above capability in disease progression/state prediction, disease progression stratification, and personalized and online prediction/monitoring for the sake of patients, physicians, caregivers, pharmaceutical companies, health maintenance organizations, and insurers, and improves its performance with the numbers of patients and their clinic visits.

### Project and Patent Status

The algorithms producing the models have already been established and evaluated. Now, these should be encapsulated into an information system with a graphical interface to finalize the product and thereby to allow patients and physicians to monitor patient disease progression, and pharma companies to evaluate the influence of a developed drug in clinical trials. Several provisional patent applications have been submitted to protect this product.

### Leading Researcher

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