Myelin Repair Foundation

Collaboration. Acceleration. Results.

INVESTING IN BIOMARKERS FOR MYELIN REPAIR

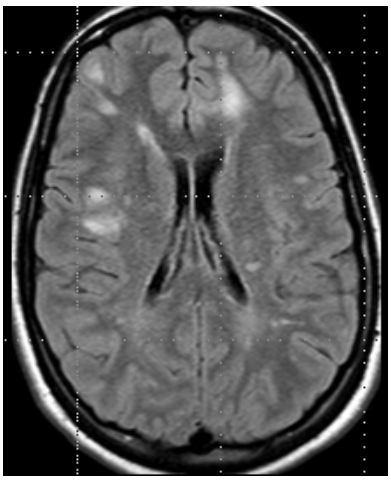
Measuring Myelin Repair in Multiple Sclerosis

Reducing the time and cost of clinical trials

Today, there are only two available ways to measure outcomes of clinical trials for new therapies for MS: Frequency of relapses and/or the rate of disease progression (e.g., the Expanded Disability Status Score or EDSS). But these measures will not necessarily be the best indicators of the effectiveness of a myelin repair treatment.

Why Won't Traditional Measures used in MS Clinical Trials Work for Myelin Repair?

- Measures of relapse are valuable when testing therapies that suppress the immune system because these therapies target the mechanisms that trigger inflammation and relapse. Because these measures do not assess actual myelin damage, it is not expected that they will be useful for evaluating treatment strategies for myelin repair or protection.
- Because the standard measures of disability (e.g., EDSS) lack sensitivity, clinical trials that depend on these measures must be lengthy and have large numbers of patients in order to generate enough data to know whether the therapy works. More importantly, measures of disability will not provide adequate data in preliminary clinical trials to make decisions about which therapies have enough promise to go on to costly more definitive testing. The cost of these cumbersome, time-consuming clinical trials poses a very real barrier to the rapid testing of large numbers of potential myelin repair therapies.

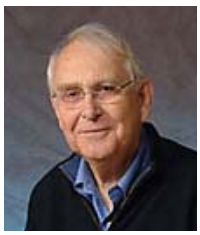


Magnetic resonance images that show myelin damage (white spots) are still being studied for their potential to measure the progress of the disease. At this time, myelin repair cannot be measured in MRI scans.

How Would Biomarkers as Measures of Myelin Repair be Different?

Biomarkers are biological tests that can be shown to correlate with some measure of disease activity. Examples of biomarkers for other diseases include blood sugar tests for diabetes or cholesterol tests for heart disease. In MS, Magnetic Resonance Imaging (MRI) is the most studied biomarker for acute disease or relapse. Unfortunately there is no consensus regarding the use of MRI to measure the progression of the disease, and certainly not myelin repair. While considerable work is currently underway to understand the ability of MRI to measure repair, the validation of a biological marker for remyelination in blood or CNS fluid would greatly facilitate the testing of new potential myelin repair therapies.

The development of biomarkers that can be used in trials of repair and protection will be essential for conducting timely and cost effective clinical trials.



The MRF Biomarker Initiative is being developed under the guidance of a Clinical Advisory Board (CAB) chaired by **Dr. Henry McFarland** (L), formerly Chief of the Neuroimmunology Branch and Director of Clinical Neuroscience at the NINDS, NIH. **Dr. Tassie Collins** (R), a Harvard Ph.D. immunologist and former Scientific Director of Neuroinflammation at Amgen has joined the MRF staff to work with Dr. McFarland and the CAB to develop the best strategy for our work in this area.

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