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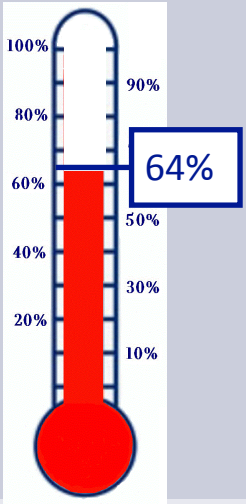
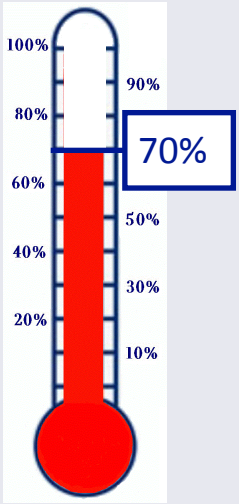
Does early treatment with highly effective DMT improve prognosis for people with MS?

WELCOME TO A JOINT DELIVER-MS AND TREAT-MS NEWSLETTER

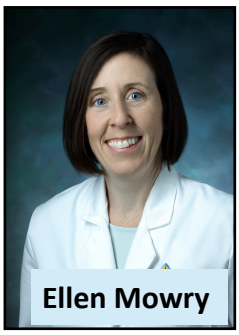
We are delighted to bring you this joint update on the partner studies: TREAT-MS and DELIVER-MS. These studies were developed in parallel and are both funded by Patient Centered Outcomes Research Institute (PCORI). The trials share a collective aim to recruit 1,700 people with MS, across over 60 sites, in order to answer the question of whether early highly effective disease modifying therapy improves outcomes for people with MS. Here we bring you key information and study updates, along with perspectives from the PIs.

Trial Name	Key Features	Enrolment
"Determining the Effectiveness of Early Intensive versus Escalation Approaches for the Treatment of Relapsing-Remitting Multiple Sclerosis" **(DELIVER MS)**	**Lead site: Cleveland Clinic** **Study population:** 800 people with RRMS. **Aim**: To compare early intensive therapy vs escalation. **Duration:** 36 months. **Primary outcome**: brain volume loss	
"TRaditional versus Early Aggressive Therapy for Multiple Sclerosis" **(TREAT MS)**	**Lead site: Johns Hopkins** **Study population:** 900 people with RRMS stratified by high-risk and low-risk for disability. **Aim**: To compare early-aggressive vs traditional therapy. **Duration**: up to 79 months. **Primary outcome:** disability progression (EDSS plus).	

FOCUS ON: TREAT-MS AND DELIVER-MS

Since the earliest stages of development, these two trials have worked together to ensure harmonised protocols that complement each other in addressing a key unanswered question for people with MS. The PIs ensured that data would be collected in such a way to allow cross-study comparisons, or pooling of the data, to power them to answer questions that may need more information than either study alone is able to provide. They also aligned on biobanking, funded by the National MS Society, with an ambition to evaluate new blood biomarkers in MS. We believe that these two studies will continue to produce important findings for years to come.


Scott Newsome


Ellen Mowry

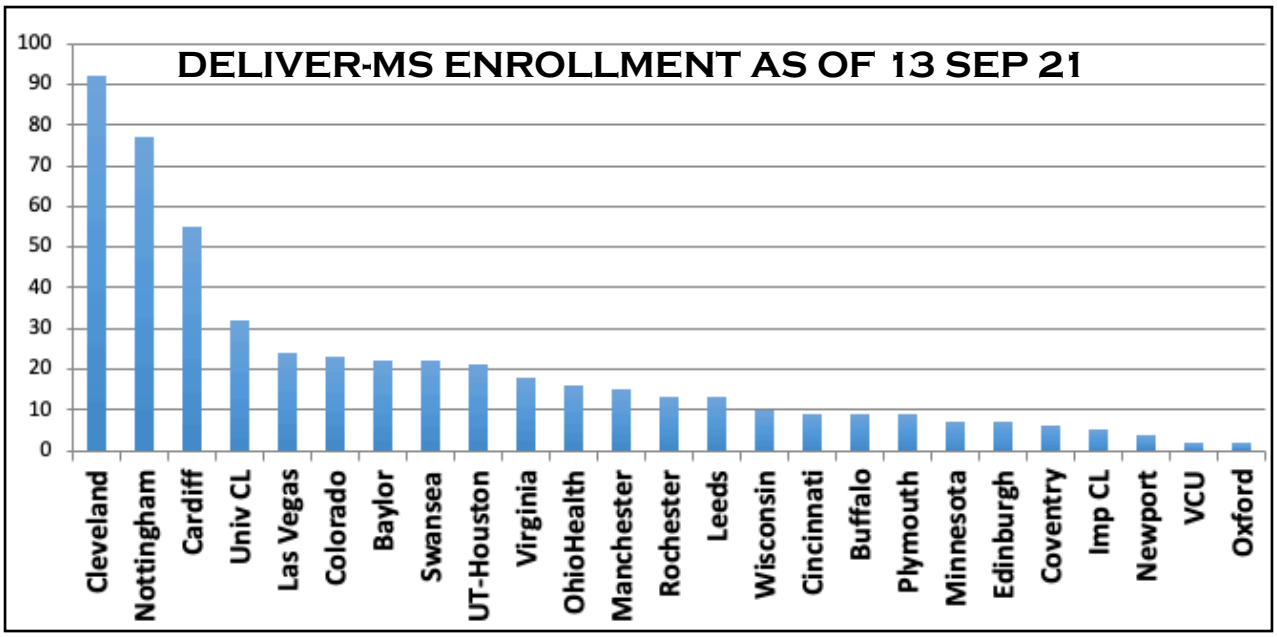
TREAT-MS, led by Ellen Mowry and Scott Newsome (PIs), will evaluate the effect of higher- vs moderate-efficacy DMTs on medium term disability, as assessed by neurological examination, walking speed and dexterity. TREAT-MS is also designed to compare whether outcomes differ in people who had mild MS at the start vs. to those who did not. In those with mild MS, TREAT-MS will explore how to best manage breakthrough activity on moderate-efficacy DMT. **DELIVER-MS**, led by Dan Ontaneda and Nikos Evangelou, tests whether escalation is a valid initial approach to DMT when combined with proactive monitoring, allowing prompt transition to high efficacy DMT in people with breakthrough MS activity. DELIVER-MS has brain volume loss as a primary outcome, with a range of secondary outcomes e.g. disability and quality of life.


Dan Ontaneda


Nikos Evangelou

We asked Ellen Mowry how relevant these studies are in 2021:

" These studies are as relevant as ever. Emerging data on certain DMTs regarding COVID-19 risk/ vaccine efficacy underscores the equipoise of these studies. It may be that the benefit derived from high efficacy DMTs is "worth it" and supersedes any risk, but we think the pandemic has heightened people's awareness of risk vs. benefit. We think TREAT-MS and DELIVER-MS will greatly improve the ability for clinicians to guide people with MS in the future, with respect to treatment choices at the time they are starting their first DMT."



FINAL THOUGHTS

We hope you enjoyed hearing about how the international MS research community has come together to develop and recruit to these two trials. We thank you again for your continued commitment to answering this important research question and look forward to providing you with further updates on TREAT-MS and DELIVER-MS as we approach our recruitment targets.

Relevant Links

DELIVER-MS website:
www.deliver-ms.com

TREAT-MS website:
https://treat-mstrial.org/

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