

NARCRMS Update

Welcome to the sixth issue of the NARCRMS Update, a quarterly publication. The North American Registry for Care and Research in Multiple Sclerosis (NARCRMS), a project of the Consortium of MS Centers (CMSC), is a physician-based registry and longitudinal database of clinical records and patient centered outcomes. NARCRMS is committed to providing clinicians and researchers with a greater, more integrated ability to track the incidence, prevalence and longitudinal history of MS. Through information sharing, NARCRMS will improve the understanding of MS and will facilitate care at every level.

General Updates

- ♦ The upgrade to the OpenClinica Platform from OC Community to OC Enterprise version 4 took place on May 15th. The upgrade makes NARCRMS 21 CFR Part 11 compliant, will assist in the inclusion of patient reported outcomes (PROs), and allow for conduct of clinical trials within the OpenClinica platform. As a result of the upgrade, the NARCRMS OpenClinica URL has changed, remember to update your bookmarks/shortcuts:

New Production URL: <https://s-3.eclinicalhosting.com/OpenClinica>

New Test URL: <https://s-3-test.eclinicalhosting.com/OpenClinica>

- ♦ The NARCRMS Steering Committee unanimously agreed to decrease the size of the committee count to 10 – 12 members to include site investigators and non-investigator MS experts who have an invested interest in NARCRMS; June Halper, Dr. Rammo-han and Dr. Li will continue as ex-officio members. The revamp of the Steering Committee is currently underway; more information to come about membership.
- ♦ The Neuroimaging Core is working diligently with sites to ensure the upload of quality scans that adhere to CMSC guidelines.

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Winners of the Spring 2019 Enrollment Competition

NACRMS pleased to announce winners of the Spring 2019 Enrollment Competition held from March 12—April 30, 2019 :

1. First Place: Swedish Hospital Center—16 enrollments and 13 completed enrollments
2. 2nd Place: Providence MS Center—9 enrollments and 7 completed enrollments
3. 3rd Place: University of Pennsylvania—4 enrollments and 5 completed enrollments

CMSC 2019 NACRMS Meetings and Abstracts May 28 - June 1, 2019 - Seattle, Washington

NACRMS will host the following meetings during the CMSC 2019 Annual Meeting:

- NACRMS Investigator Reception & Dinner - Site Investigators & Coordinators are invited to join the NACRMS Leadership for a Reception & Dinner at the CMSC 2019 Annual Meeting. The Reception & Dinner will be held on Wednesday, May 29, 2019 from 7PM PT to 9PM PT at the Sheraton Grand Seattle – Ravenna Room.
- NACRMS IAB & HEOR Breakfast Meeting - Members of the Industry Advisory Board and HEOR are invited to join NACRMS Leadership for a Breakfast Meeting at the CMSC 2019 Annual Meeting. The Breakfast Meeting will be held on Thursday, May 30, 2019 from 7AM to 9AM PT at the Sheraton Grand Seattle – Ravenna Room.

NACRMS Abstracts at the CMSC 2019 Annual Meeting:

- Abstract ID# 6188, "The North American Registry for Care and Research in Multiple Sclerosis (on behalf of the NACRMS Site PIs)" – CMSC will display posters starting on Tuesday, May 28 at 12:00 PM. The official Poster Session will take place on Thursday, May 30 at 6:45 pm.
- Abstract ID# 6241, "The Economic Impact of Multiple Sclerosis: A Preliminary Look at the North American Registry for Care and Research in Multiple Sclerosis (NACRMS) (on behalf of the NACRMS HEOR Advisory Group)" will have a platform presentation on Friday, May 31, 2019 from 3:40 to 4:00 PM.

Spotlight: Dr. Anne H. Cross

NARCRMS PI, Dr. Anne H. Cross, from Washington University, St. Louis, was awarded the 2019 John Dystel Prize for MS Research on May 8, 2019, at the Annual Meeting of the American Academy of Neurology in Philadelphia.



Dr. Anne H. Cross

Dr. Cross was chosen by a committee of her peers to receive the National MS Society/American Academy of Neurology's 2019 John Dystel Prize for Multiple Sclerosis Research. Her many research interests and successes include early work on the key role of B lymphocytes (immune cells) in helping to drive immune attacks in MS animal models and in people with MS. She also pioneered new imaging techniques to track MS disease activity, and has explored the potential benefits of calorie restriction.

Prof. Cross received early fellowship support from the National MS Society, including a Harry Weaver Neuroscience Scholar Award in 1990, a five-year career development award given to young scientists who are judged to have promising futures. That promise has been fulfilled in many contributions to the understanding and treatment of MS, including:

- **Identifying the role of B cells in MS lesion formation and disease course**, which led to the first therapies targeting B cells, a type of immune cell. Her research has also been critical in identifying how these immune cells lead to central nervous system injury.
- **Pioneering the first clinical trial of rituximab**, a B cell-depleting therapy, with funding from the National MS Society. Her studies with rituximab in people who were not helped by other treatments, began in early 2002 and helped pave the way for the FDA's 2017 approval of ocrelizumab (Ocrevus), the first approved therapy for primary progressive multiple sclerosis (PPMS); it is also approved for relapsing forms of MS. Prof. Cross continues to work on how B cell depletion can be beneficial for treating MS. "We still don't know exactly how B cell depletion works or why B cells are so critical in MS activity," she notes.
- **Society-sponsored work contributing to the development of imaging techniques** used to investigate progressive MS and nerve damage. Finding biomarkers that show progression before a person's progressive disease is revealed on a clinical examination may lead to earlier and more targeted treatments for progressive MS.
- **Showing that calorie restriction can improve the course of disease** in animal models of MS. This has led to several clinical trials in MS testing strategies such as intermittent fasting.
- **Sharing knowledge.** She has mentored and trained numerous colleagues, many of whom have gone on to do important work in the field. Prof. Cross has also served as a volunteer peer reviewer of research proposals for agencies including the National MS Society, and was Chair of the Society's Research Programs Advisory Committee.

National Multiple Sclerosis Society. (2019). 2019 John Dystel Prize for MS Research Goes to Prof. Anne Cross, Who Championed the Role of B Cells in MS. Retrieved May 14, 2019, from <https://www.nationalmssociety.org/About-the-Society/News/2019-John-Dystel-Prize-for-MS-Research-Goes-to-Pro>

Enrollment Update

NARCRMS is currently enrolling patients at 21 MS Centers. Included below is a summary update of enrollments as of May 22, 2019.

MS Center:	# of Patients Enrolled:	# of Patients in Screening	# of Completed Enrollments:
MS Clinic of Central Texas	22	0	8
University of Texas HSC - Houston MS Research Group	8	0	0
University of Miami – MS Center	51	0	50
University of Pennsylvania – MS Research Center	27	0	23
Washington University in St. Louis	41	0	33
The Ohio State University	6	0	6
Rutgers University	26	1	22
San Juan MS Center	52	0	50
University of Michigan	48	2	42
Mandell Center for Comprehensive MS Care & Neuroscience Research	51	15	48
University of Florida	12	0	12
Fort Wayne Neurological Center	11	0	11
Hackensack Meridian	9	0	8
Memorial Health System	17	0	17
Providence MS Center	26	0	25
Stanford MS Center	0	0	0
Swedish Hospital Center	47	0	46
University of Maryland	27	0	27
University of New Mexico	0	0	0
Northwestern University	1	0	0
Northwell Health/Lenox Hill	0	0	0
University of Saskatchewan	0	0	0
Total Number of Patients:	482	18	428

Goals of NARCRMS:

Over the next few years, NARCRMS plans to :

- ◇ Launch 4 additional sites for enrollment
- ◇ Enroll at least 1,000 patients across 20 to 26 sites
- ◇ Activate Cores of Excellence, including:
 - * Neuroimaging Core
 - * Biomarker Core
 - * Genetics Core
 - * Bioinformatics/ Biostatistics Core
 - * Neuropathology and Brain Banking Core
 - * Healthcare Economics Core
- ◇ Provide enrolled patients the ability to record Patient Reported Outcomes directly into the NARCRMS registry.
- ◇ Provide an infrastructure for industry supporters to better enroll and conduct clinical trials.
- ◇ Provide clinicians with a better understanding of the impact of treatment modalities on disease progression.

Report from the North American MS Registries Meeting

The second annual North American MS Registries Meeting was held in Philadelphia, PA on May 3, 2019. The meeting was a great success with over 30 individuals in attendance representing 13 different registries, the NMSS, CMSC, NIH/NINDS, PCORI, CDC and industry.

Topics of discussion during the morning session included a report on the International MS Registry Meeting from Dr. Ellen Mowry, a discussion about the democratization of biomedical data related to MS from Dr. Sergio Baranzini and an overview of the NINDS common data elements (CDEs) from Dr. Ursula Utz. During the afternoon session, attendees shared their insights and suggestions about how to harmonize and share data across registries and discussed four pilot proposals submitted by Dr. Amber Salter, Ms. Sara Loud (2x) and Dr. Mitchell Wallin that would take advantage of data sharing from different registries to study progression.

Feedback was requested from attendees about how to proceed and overwhelmingly, attendees suggested the creation of a catalogue or registry of North American MS Registries. The CMSC, NMSS and NIH/NINDS will continue discussions about the creation of a catalogue or registry of North American MS Registries.

Announcements

- ◆ Sites should remember to invoice NARCRMS for every 5 completed enrollments and annual follow up visits. Please send invoices to: NARCRMSOpsCenter@s-3.com
- ◆ As a reminder the NARCRMS Leadership has temporarily lifted the enrollment cap of 50 enrollments per site. Sites that have already reached 50 enrollments can continue enrolling patients until otherwise notified.

