Multiple Sclerosis Outcome Assessments Consortium (MSOAC)

MSOAC Data Acquisition Highlights

National Multiple Sclerosis Society

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Presented by Jesse Cedarbaum (Biogen) on behalf of Richard Rudick and the MSOAC Consortium

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The Genesis of the MSOAC

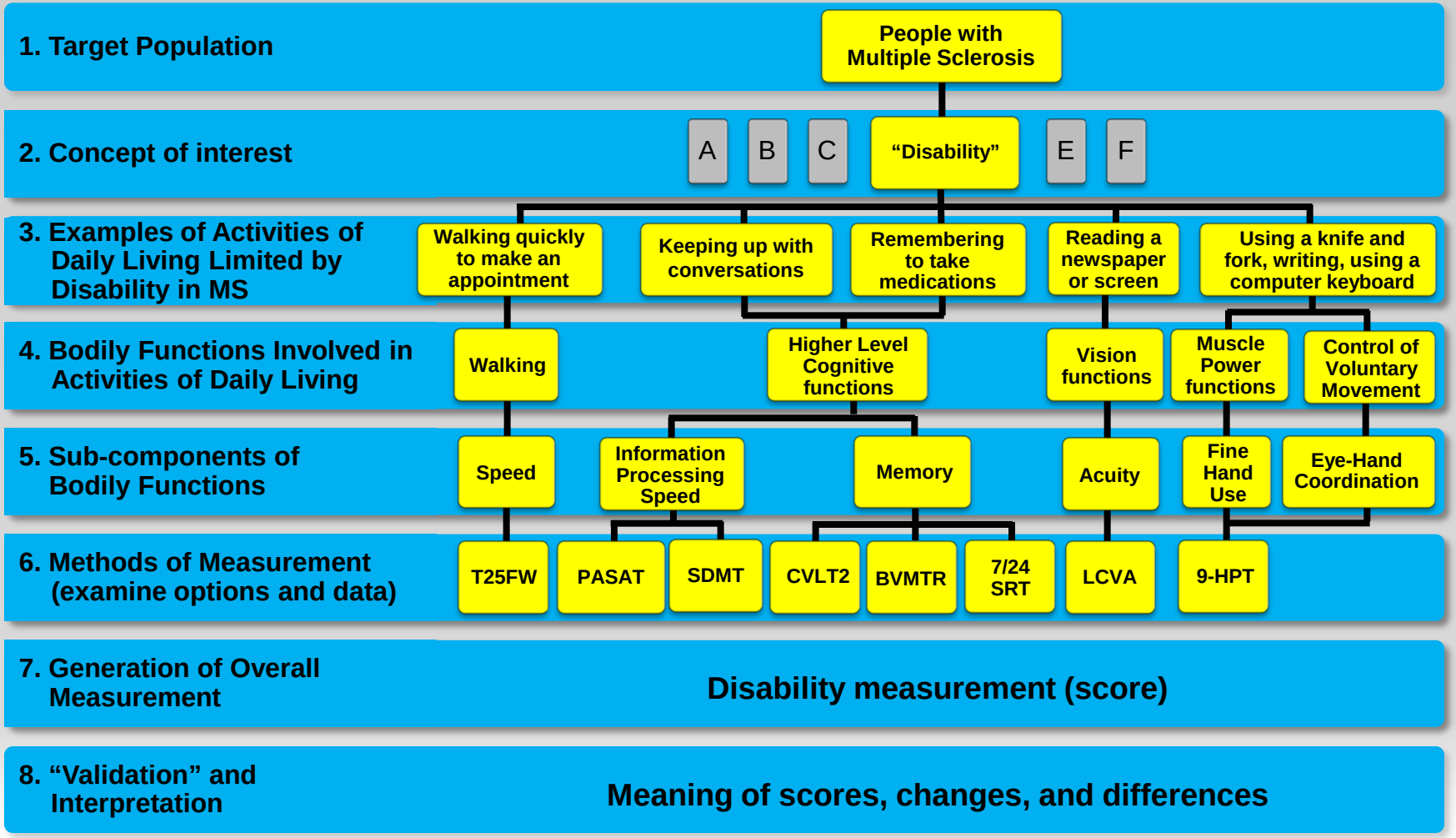
- **May 2011 - NMSS-ECTRIMS Workshop on Disability Outcome Measures in MS**
  - Recommendations for further improvement in MS disability outcome measures (Cohen et al., Lancet Neurology 11:467-476, 2012).
- **December 2011 – MSFC Task Force Meeting**
  - General agreement on the value of analyzing existing clinical trial data to optimize a clinical outcome measure (Ontaneda et al., Multiple Sclerosis Journal 18(8):1074-1080, 2012).

The Mission of MSOAC

The Multiple Sclerosis Outcome Assessments Consortium (MSOAC), funded by the National MS Society, aims to:

- *Evaluate existing clinical trial data to qualify a new primary clinical outcome assessment (COA) measure for disability in MS clinical trials. The new measure will be designed to reflect disease progression, assessing the impact of new treatments intended to slow or stop the neuropathological changes associated with MS.*

Framework for Developing a COA Performance Measure for MS Clinical Trials



MSOAC Specific Research Aims

1. Create MS therapeutic area data standards, leveraging efforts already underway.
2. Remap existing MS clinical trial data into common MS therapeutic area data standards.
3. Create an online MS database of aggregated, standardized clinical data, and make the placebo arm of the database available to qualified researchers.
4. Create scientific consensus on the optimal components of a new Performance Outcome (PerfO) measure.
5. Advance a new PerfO measure to the FDA and EMA for qualification for use as a primary endpoint in MS clinical trials.

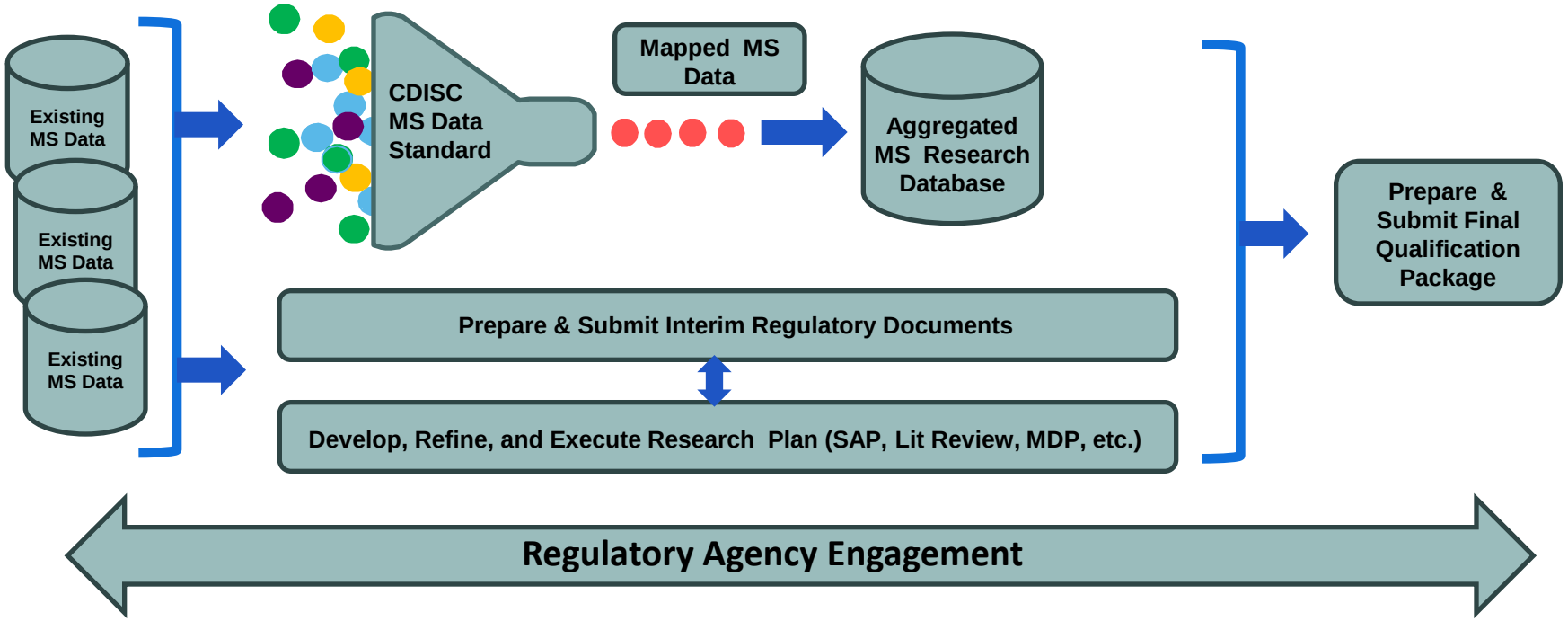
Key: Establishing Clinical Meaningfulness

- A priority global aim of MSOAC is to contribute evidence towards the meaningfulness in the lives of persons with MS of walking speed, dexterity, visual acuity, and speed of information processing.

- MSOAC has identified three approaches that will be used in this regard:
  1. A Literature Review
  2. The Modified Delphi Process ("Voice of the Patient")
  3. Analysis of data from PRO instruments in the contributed datasets

MSOAC Project Overview

- Develop and support adoption of a clinical outcome assessment tool, and obtain regulatory qualification for use as a primary or secondary endpoint in MS clinical trials.
- The qualified methodology will measure neuroperformance and will be sensitive to limitations in daily living activities of patients affected by MS.



MSOAC Data Acquisition Status

Study	n	Type	CT.gov #	EDSS	FSS	T25FW	9HPT	PASAT	LCVA	SDMT	Image	PROs
AFFIRM	939	RRMS	NCT00027300	√	√	√	√	√	√	No	√	MSQLI, BDI-II
SENTINEL	1196	RRMS	NCT00030966	√	√	√	√	√	√	No	√	MSQLI, BDI-II
CombiRx	1008	RRMS	NCT00211887	√	√	√	√	√	√	No	√	MSQLI, Rankin
FREEDOMS	1272	RRMS	NCT00289978	√	√	√	√	√	√	No	√	EQ5D
FREEDOMS 2	1083	RRMS	NCT00355134	√	√	√	√	√	√	No	√	EQ5D,FIS,Primus
TRANSFORMS	1292	RRMS	NCT00340834	√	√	√	√	√	√	No	√	EQ5D,FIS,Primus
CARE-MS 1	581	RRMS	NCT00530348	√	√	√	√	√	√	No	√	EQ5D,FAMS,SF-36
CARE-MS 2	840	RRMS	NCT00548405	√	√	√	√	√	√	No	√	EQ5D,FAMS,SF-36
TEMSO	1088	RRMS	NCT00134563	√	√	√	√	√	No	No	No	EQ5D,FIS,SF-36
CLIMB	200	RRMS	N/A	√	No	√	√	No	√	√	√	MSQOL54, SF-36
STRATA	1094	RRMS	NCT00297232	√	No	No	No	√	No	√	√	MSHQ, BDI, NCQ
ADVANCE	1512	RRMS	NCT00906399	√	No	√	√	√	VFT	√	√	EQ-5D, MSIS, SF12
RRMS = 12	**12105**			**11905 Received**			**200 In-Process**					
IMPACT	434	SPMS	N/A	√	√	√	√	√	No	No	√	MSQLI, BDI-II
MAESTRO	610	SPMS	NCT00869726	√	√	√	√	√	No	No	√	MSQOL54
PROMISE	943	PPMS	N/A	√	√	√	√	√	No	No	√	MSQLI
INFORMS	969	PPMS	NCT00731692	√	?	√	?	?	?	No	√	?
OLYMPUS	439	PPMS	NCT00087529	√	√	√	√	√	?	?	?	?
S/PPMS = 5	**3395**			**1987 Received**			**1408 In-Process**					
MS-F203	301	All	NCT00127530	√	No	√	No	No	No	No	No	MSWS-12
MS-F204	239	All	NCT00483652	√	No	√	No	No	No	No	No	MSWS-12
All MS = 2	**540**			**540 Received**			**0 In-Process**					
Total = 19	**16040**			**14432 Received**			**1608 In-Process**					

MSOAC Data Highlights

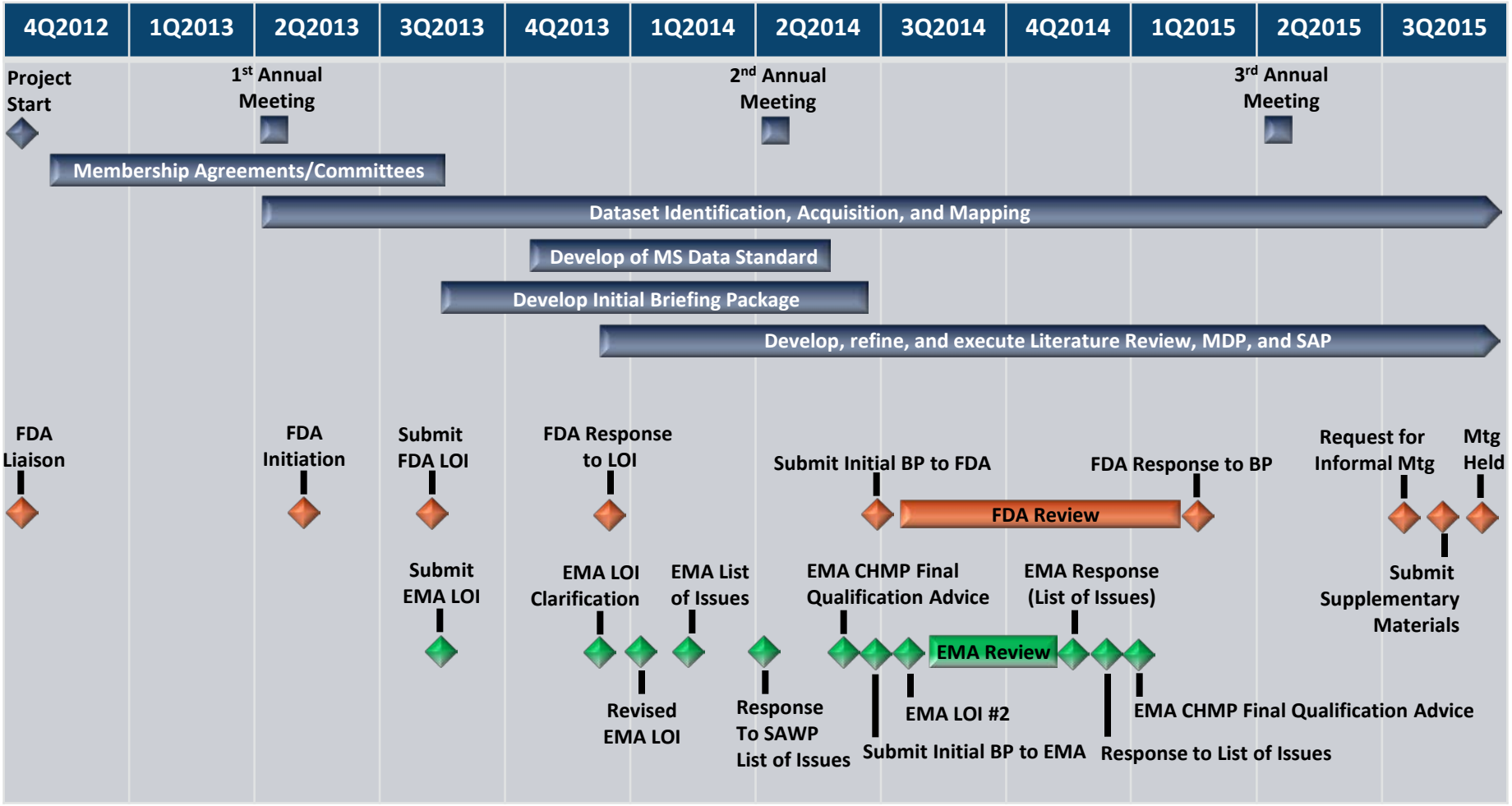
New MS Data Standard

- CDISC Version 1.0 MS Therapeutic Area Data Standard published on May 2nd, 2014.
- Version 2 (primarily to address imaging data) is in-process

Data Acquisition and Mapping Status (currently in-process)

- Total Subjects In-House = 14,432 (RR = 11,905, PP = 2517)
  - Treatment Arm Subjects = 11,454
  - Placebo Arm Subjects = 2,978
- Percent of data mapped currently to CDISC MS Data Standard = 70%

MSOAC Timeline: Project and Regulatory Milestones



Thank You!

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