# COVID-19 and the MULTI-ACT model

**10th of July 2020**

Paola Zaratin, Director of Scientific Research, Italian MS Society

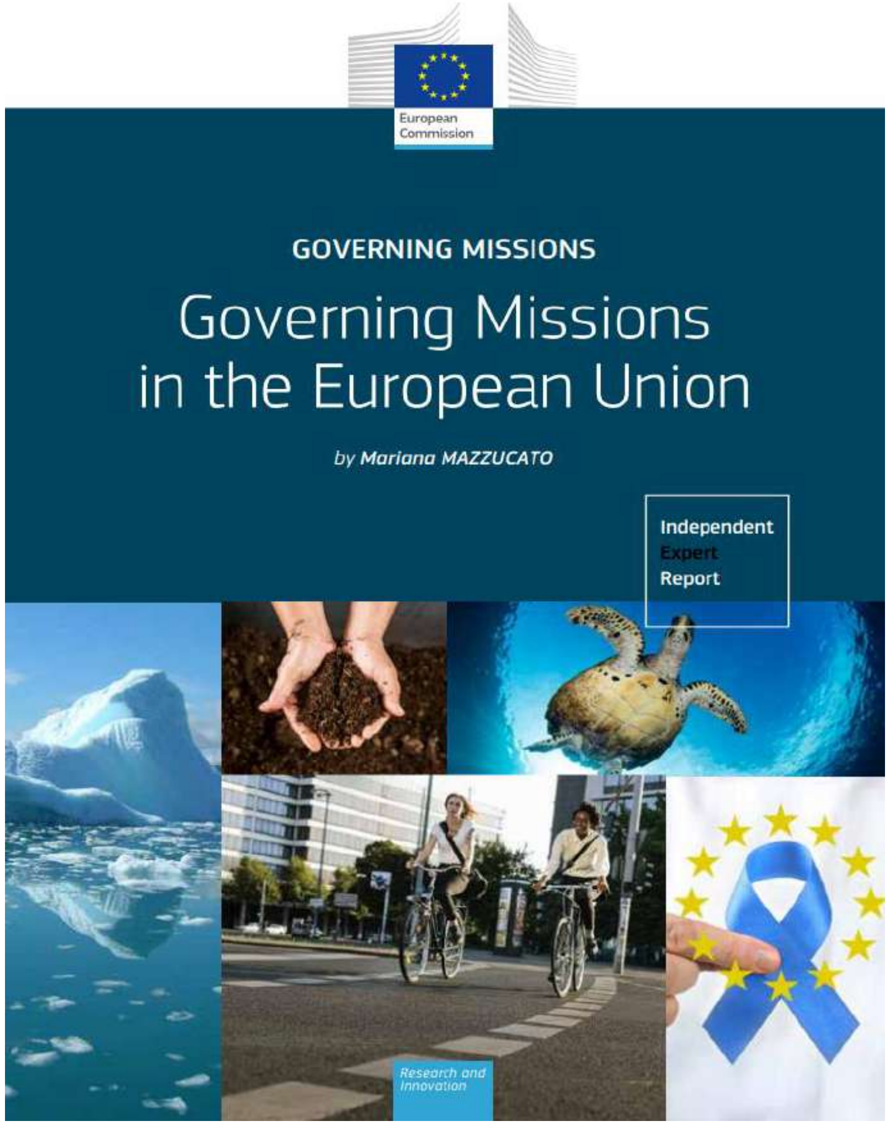
MULTI-ACT project coordinator

Multi-Act
This project has received funding from the European Union's
Horizon 2020 Research and Innovation Programme under the
Grant Agreement No. 787570

# TODAY'S DISCUSSION

1. COVID-19 PANDEMIC CALLS FOR RESPONSIBLE RESEARCH & INNOVATION
2. HOW MULTI-ACT HELPS MEETING THE CHALLENGE
3. TESTING THE MODEL ON MS
4. TAKE HOME MESSAGES

# COVID-19 PANDEMIC CALLS FOR A MISSION-ORIENTED MODEL


European Commission

GOVERNING MISSIONS

Governing Missions in the European Union

by Mariana MAZZUCATO

Independent Expert Report

Research and Innovation

***https://ec.europa.eu/info/sites/info/files/research_and_innovation/contact/documents/ec_rtd_mazzucato-report-issue2_072019.pdf***

*"Missions provide a massive opportunity to increase the impact of European research and innovation, grasp the public imagination and make real progress on complex challenges" Mariana Mazzucato*


## The Big Failure of Small Government

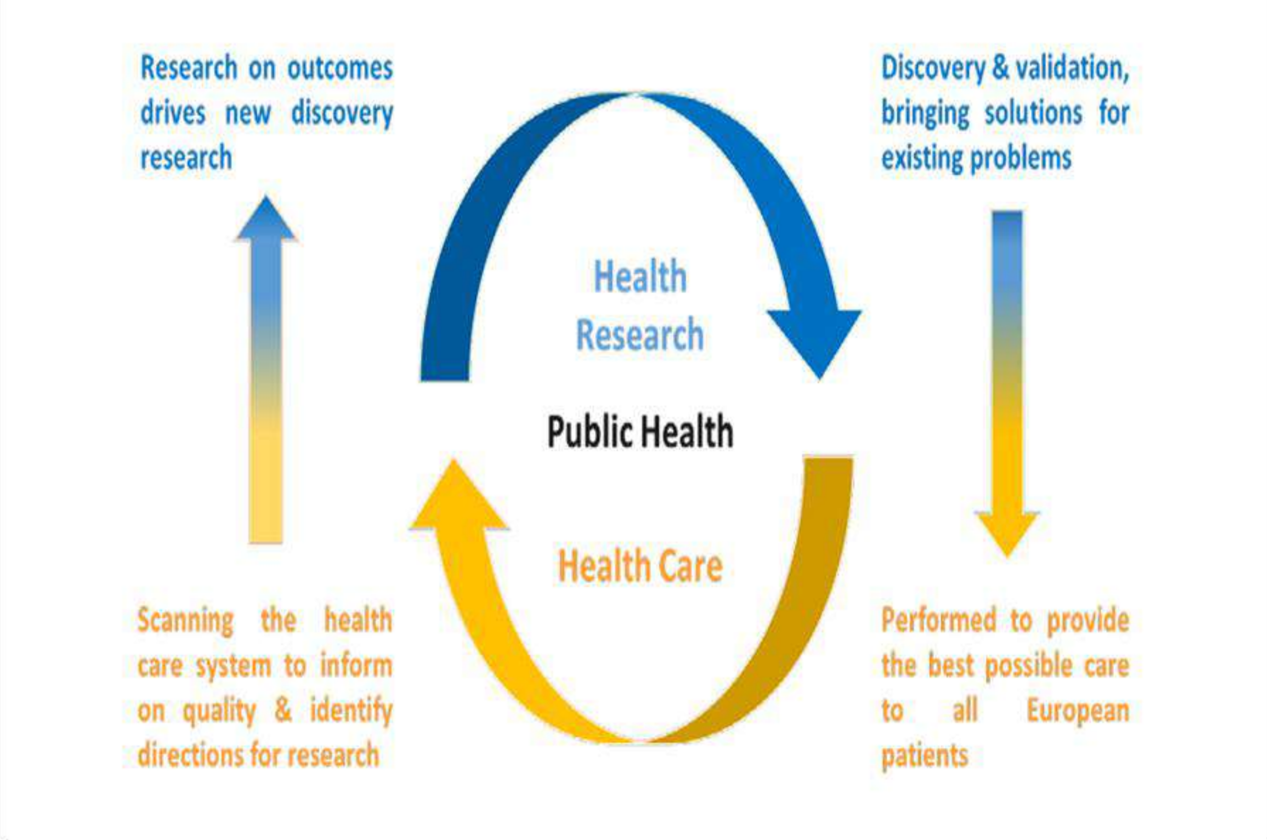
*May 19, 2020* | MARIANA MAZZUCATO, GIULIO QUAGGIOTTO

*It is no coincidence that countries with mission-driven governments have fared better in the COVID-19 crisis than have countries beholden to the cult of efficiency. Effective governance, it turns out, cannot be conjured up at will, because it requires investment in state capacity.*

***https://www.project-syndicate.org/commentary/small-governments-big-failure-covid19-by-mariana-mazzucato-and-giulio-quaggiotto-2020-05?barrier=accesspaylog***

# COVID-19 PANDEMIC
# CALLS FOR HEALTH RESEARCH AND CARE UNIQUE ECOSYSTEM

*The discovery and implementation process: iterations between health research and health care*



Research on outcomes drives new discovery research

Discovery & validation, bringing solutions for existing problems

Health Research

Public Health

Health Care

Scanning the health care system to inform on quality & identify directions for research

Performed to provide the best possible care to all European patients

*Adapted from Building the future of health research .Proposal for a European Council for Health Research. A consensus document of the H2020 Scientific Panel for Health, 2018*

# ITALIAN PROGRAM COVID-19 & MULTIPLE SCLEROSIS

## HOW TO ENSURE IMPACT OF COVID-19 RESEARCH ON SOCIETY?

- The Italian Multiple Sclerosis Society (AISM) and its Foundation (FISM), and the Multiple Sclerosis Study Group of the Italian Neurological Society (SIN), have set up a Research Program that is meant to represent an answer, as complete as possible, to this unprecedented event.
- Multiple Sclerosis and COVID-19 (MuSC-19) platform dedicated to collect national and international clinical data that is collecting clinical data to evaluate the impact of COVID-19 infection on people affected by MS [https://musc-19.dibris.unige.it/](https://musc-19.dibris.unige.it/)

UNIVERSITÀ DEGLI STUDI DI GENOVA

MuSC-19

SOCIETÀ ITALIANA DI NEUROLOGIA

Platform donated by Roche

ONE THOUSAND FOURTEEN PATIENTS

→ 843 Cases from 84 MS Italian Sites

→ 171 Cases from 9 International Sites

The thinking underling Responsible Research Innovation wants to challenge our notion of good science as such.

It argues that excellence, validity and relevance are connected by engaging patients  and society in the research continuum as key stakeholder with decision making role multi-act

*Contact details:*

**SCIENTIFIC COORDINATION**
Italian Multiple Sclerosis
Society Foundation
Paola Zaratin
multi-act@aism.it

**PROJECT DISSEMINATION**
European Brain Council
multiact@braincouncil.eu

Website: www.multiact.eu

The **MULTI-ACT** project started on 1 May 2018 and will continue for three years. It brings together leading European society, patients, patient organizations, research/academic institutions, governmental organizations, and technological organizations. The consortium forms a **multidisciplinary network** that integrates and coordinates various competences in related areas of the work that will be undertaken.

The project is coordinated by the **Italian Multiple Sclerosis Society Foundation**, as member of the International MS Federation, a "boundary organization" between science and patients.

*The MULTI-ACT partners are:*

- Fondazione Italiana Sclerosi Multipla FISM Onlus
- Università degli Studi di Trento
- Ernst & Young Financial Business Advisors SpA
- Universidad de Burgos
- Tampereen Yliopisto
- The European Brain Council AISBL
- Intrasoft International SA
- European Health Management Association
- Fondation Pour L'aide a la Recherche sur la Slerose en Plaques
- Dane-i-Analizy.pl sp zoo
- Universidade Catolica UCP Portuguesa

*A new mission-oriented model for collective sustainability*

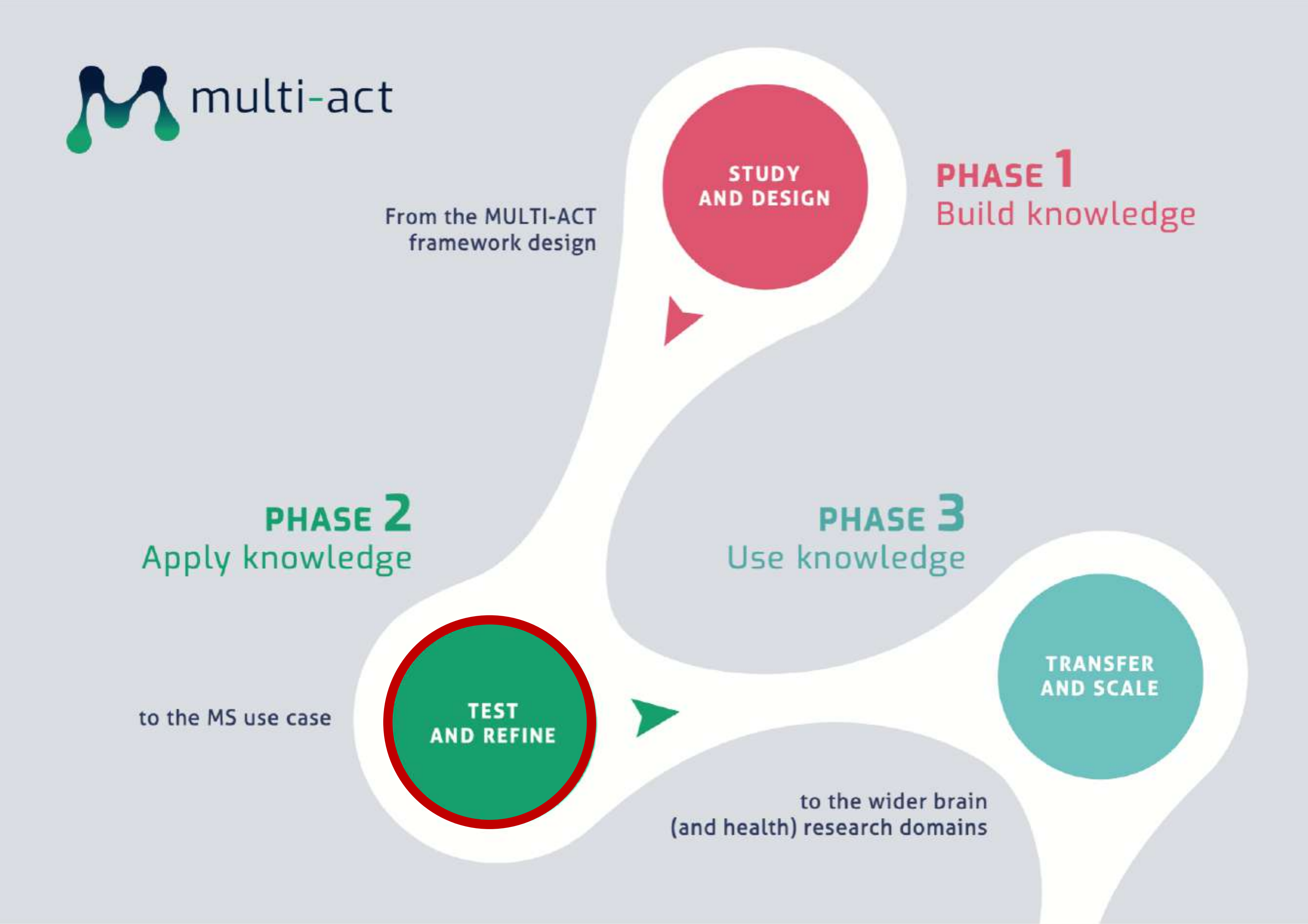
multi-act

**HELPS MEETING THE CHALLENGE**

# A Collective Research Impact Framework and multi-variate models to foster the true engagement of actors and stakeholders in Health Research and Innovation

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under the Grant Agreement No. 787570

# THE MULTI-ACT JOURNEY



PHASE 1
Build knowledge

STUDY AND DESIGN

From the MULTI-ACT framework design

PHASE 2
Apply knowledge

TEST AND REFINE

to the MS use case

PHASE 3
Use knowledge

TRANSFER AND SCALE

to the wider brain (and health) research domains

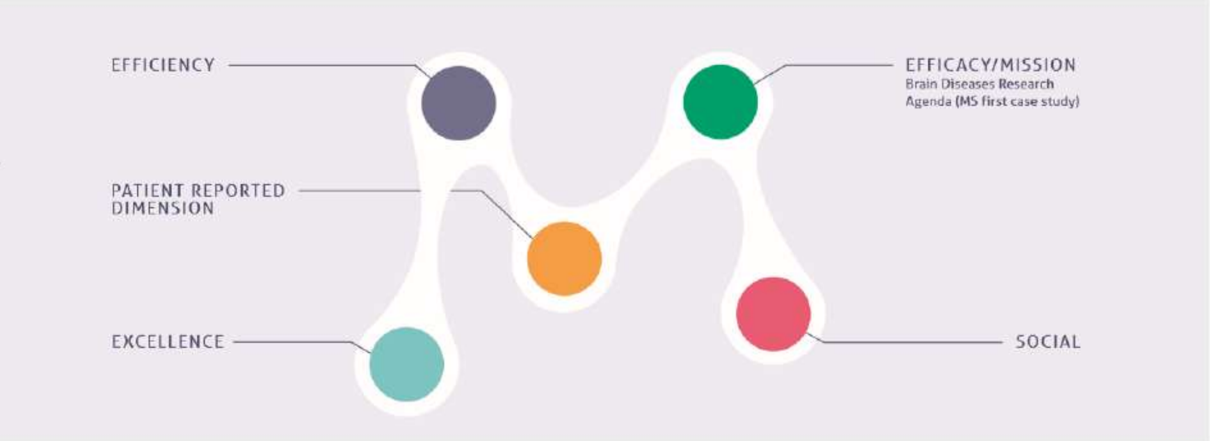
# The MULTI-ACT FRAMEWORK

## The governance model

- Mission & agenda
- Participatory governance
- Clear, effective and inclusive methodology stakeholder engagement
- Effective and efficient management and coordination of the initiative
- Co-accountability mesurement

## The MULTI-ACT patient engagement strategy across the seven steps of the R&I path

## The impact assessment scorecard

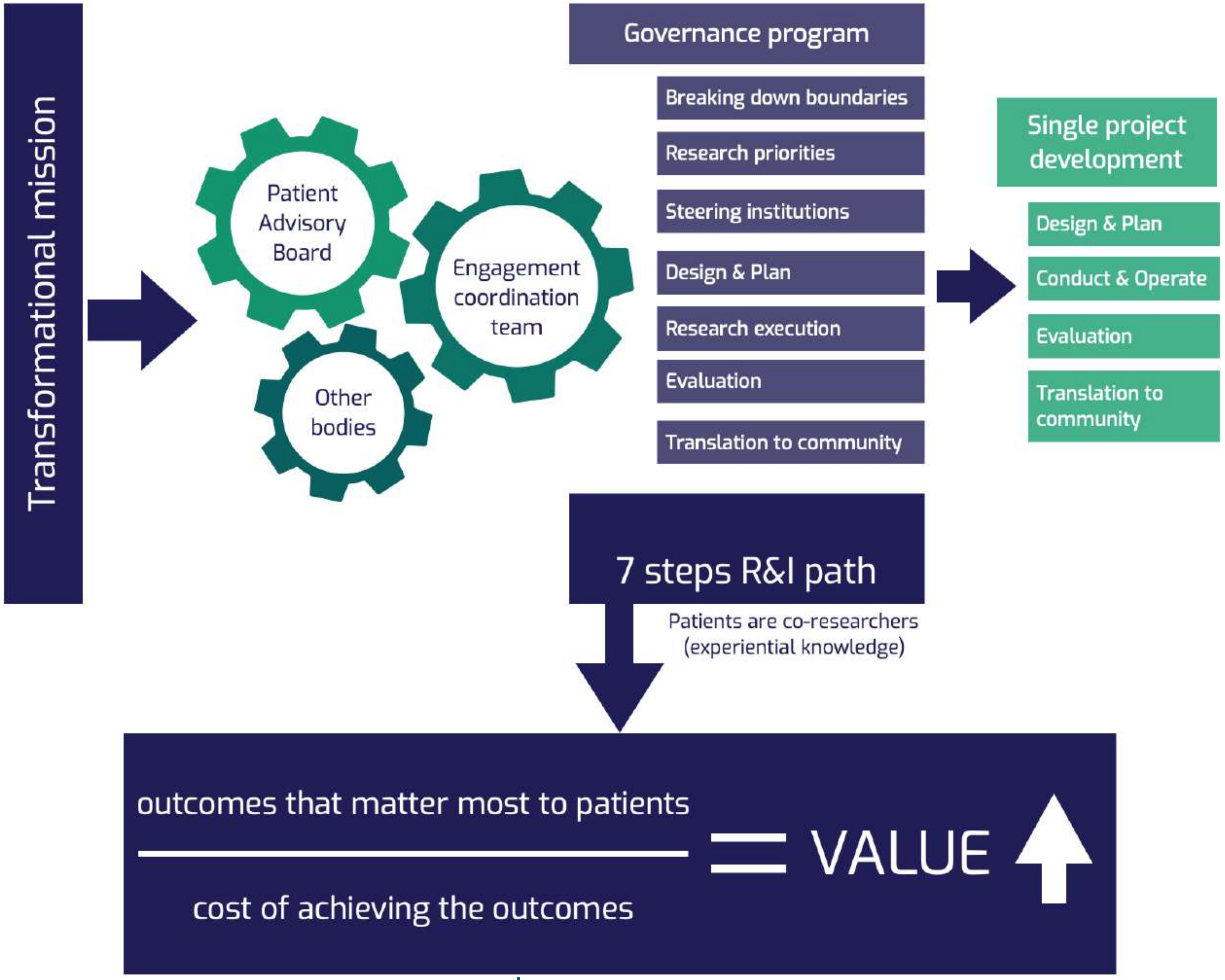


## A suite of tools for Multi-Stakeholder Health Research Initiatives

A **digital toolbox** to support multi-stakeholder health research promoters **applying the MULTI-ACT framework**

A set of **guidelines** to assist multi-stakeholder health research promoters in the **use of integrated collective research impact framework**

# THE VALUE OF THE PATIENT ENGAGEMENT



Transformational mission

Patient Advisory Board

Engagement coordination team

Other bodies

**Governance program**

- Breaking down boundaries
- Research priorities
- Steering institutions
- Design & Plan
- Research execution
- Evaluation
- Translation to community

**Single project development**

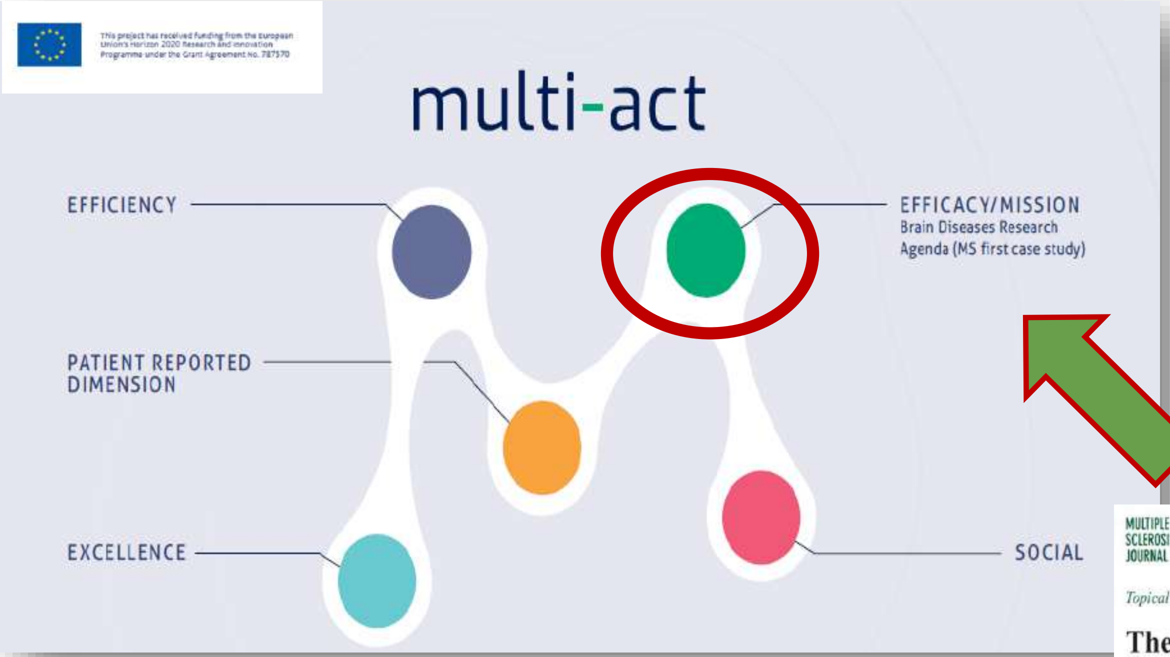
- Design & Plan
- Conduct & Operate
- Evaluation
- Translation to community

**7 steps R&I path**

Patients are co-researchers (experiential knowledge)

$$\frac{\text{outcomes that matter most to patients}}{\text{cost of achieving the outcomes}} = \text{VALUE} \uparrow$$

# MULTI-ACT CASE STUDY
# MULTIPLE SCLEROSIS CARE UNIT


This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under the Grant Agreement No. 787570

multi-act

EFFICIENCY

EFFICACY/MISSION
Brain Diseases Research
Agenda (MS first case study)

PATIENT REPORTED DIMENSION

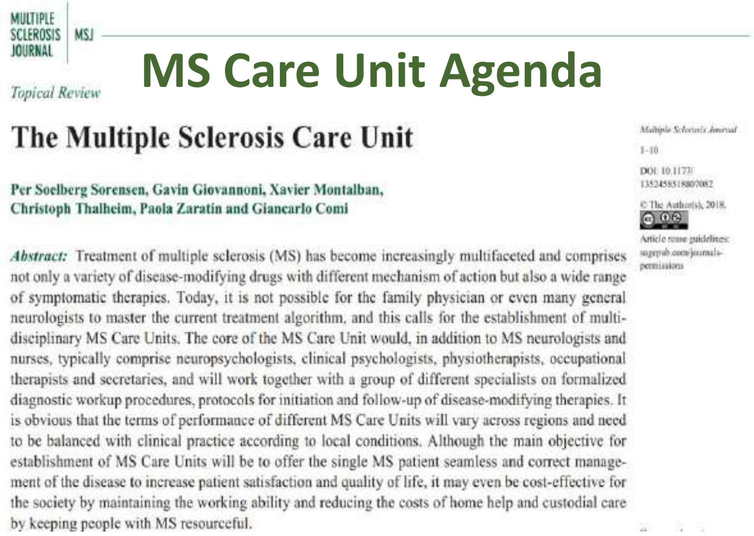
EXCELLENCE

SOCIAL

MS Initiatives

European
Charcot
Foundation

## MS Care Unit Agenda


MULTIPLE SCLEROSIS JOURNAL | MSJ

*Topical Review*

### The Multiple Sclerosis Care Unit

**Per Soelberg Sorensen, Gavin Giovannoni, Xavier Montalban, Christoph Thalheim, Paola Zaratin and Giancarlo Comi**

*Multiple Sclerosis Journal*
1–10
DOI: 10.1177/ 1352458518807082

***Abstract:*** Treatment of multiple sclerosis (MS) has become increasingly multifaceted and comprises not only a variety of disease-modifying drugs with different mechanism of action but also a wide range of symptomatic therapies. Today, it is not possible for the family physician or even many general neurologists to master the current treatment algorithm, and this calls for the establishment of multidisciplinary MS Care Units. The core of the MS Care Unit would, in addition to MS neurologists and nurses, typically comprise neuropsychologists, clinical psychologists, physiotherapists, occupational therapists and secretaries, and will work together with a group of different specialists on formalized diagnostic workup procedures, protocols for initiation and follow-up of disease-modifying therapies. It is obvious that the terms of performance of different MS Care Units will vary across regions and need to be balanced with clinical practice according to local conditions. Although the main objective for establishment of MS Care Units will be to offer the single MS patient seamless and correct management of the disease to increase patient satisfaction and quality of life, it may even be cost-effective for the society by maintaining the working ability and reducing the costs of home help and custodial care by keeping people with MS resourceful.

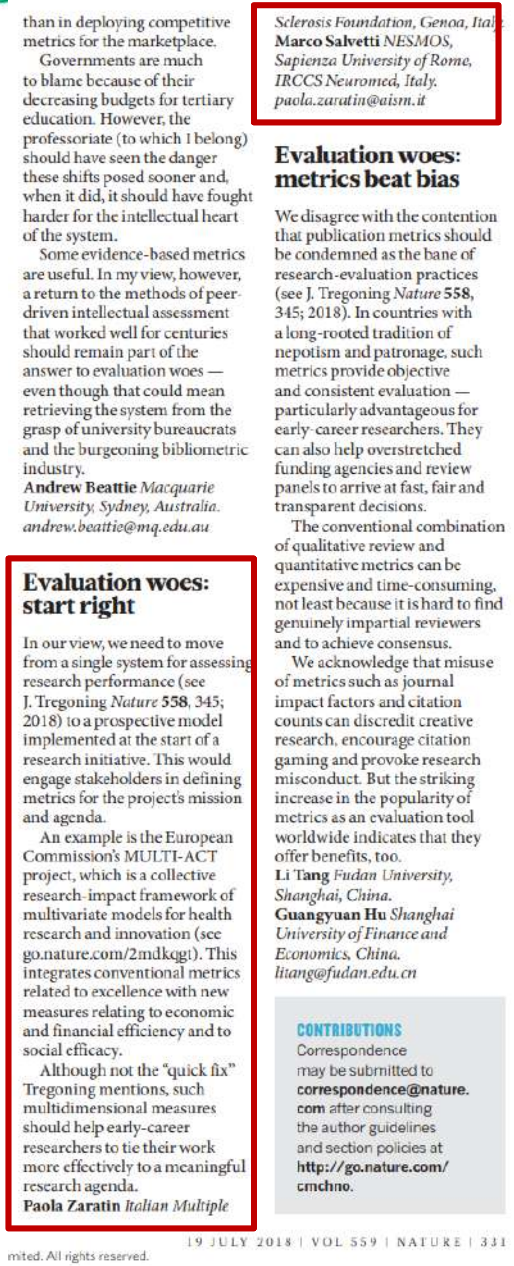
INTERNATIONAL
## PROGRESSIVE MS ALLIANCE
**CONNECT** TO END PROGRESSIVE MS

PARTNERSHIP ANNOUNCED AS PART OF WORLD MS DAY CELEBRATIONS

Alliance and MULTI-ACT partnership

NEW
HORRIZON

# INTEREST OF THE RESEARCH COMMUNITY



than in deploying competitive metrics for the marketplace.

Governments are much to blame because of their decreasing budgets for tertiary education. However, the professoriate (to which I belong) should have seen the danger these shifts posed sooner and, when it did, it should have fought harder for the intellectual heart of the system.

Some evidence-based metrics are useful. In my view, however, a return to the methods of peer-driven intellectual assessment that worked well for centuries should remain part of the answer to evaluation woes — even though that could mean retrieving the system from the grasp of university bureaucrats and the burgeoning bibliometric industry.

**Andrew Beattie** *Macquarie University, Sydney, Australia.*
*andrew.beattie@mq.edu.au*

## Evaluation woes: start right

In our view, we need to move from a single system for assessing research performance (see J. Tregoning *Nature* **558**, 345; 2018) to a prospective model implemented at the start of a research initiative. This would engage stakeholders in defining metrics for the project's mission and agenda.

An example is the European Commission's MULTI-ACT project, which is a collective research-impact framework of multivariate models for health research and innovation (see go.nature.com/2mdkqgt). This integrates conventional metrics related to excellence with new measures relating to economic and financial efficiency and to social efficacy.

Although not the "quick fix" Tregoning mentions, such multidimensional measures should help early-career researchers to tie their work more effectively to a meaningful research agenda.

**Paola Zaratin** *Italian Multiple Sclerosis Foundation, Genoa, Italy.*
**Marco Salvetti** *NESMOS, Sapienza University of Rome, IRCCS Neuromed, Italy.*
*paola.zaratin@aism.it*

## Evaluation woes: metrics beat bias

We disagree with the contention that publication metrics should be condemned as the bane of research-evaluation practices (see J. Tregoning *Nature* **558**, 345; 2018). In countries with a long-rooted tradition of nepotism and patronage, such metrics provide objective and consistent evaluation — particularly advantageous for early-career researchers. They can also help overstretched funding agencies and review panels to arrive at fast, fair and transparent decisions.

The conventional combination of qualitative review and quantitative metrics can be expensive and time-consuming, not least because it is hard to find genuinely impartial reviewers and to achieve consensus.

We acknowledge that misuse of metrics such as journal impact factors and citation counts can discredit creative research, encourage citation gaming and provoke research misconduct. But the striking increase in the popularity of metrics as an evaluation tool worldwide indicates that they offer benefits, too.

**Li Tang** *Fudan University, Shanghai, China.*
**Guangyuan Hu** *Shanghai University of Finance and Economics, China.*
*litang@fudan.edu.cn*

**CONTRIBUTIONS**
Correspondence may be submitted to **correspondence@nature.com** after consulting the author guidelines and section policies at **http://go.nature.com/cmchno.**

mited. All rights reserved.

19 JULY 2018 | VOL 559 | NATURE | 331

---

## Patient-reported outcomes in the spotlight

CrossMark

The importance of patients' perspectives on their disease status and quality of life is well recognised as an essential part of research studies and neurological practice. How best to incorporate patient-reported outcomes (PROs) in clinical studies and, eventually, into clinical practice remains a matter of debate. The use of PROs is especially challenging for neurological diseases, considering that patients are usually old, fragile, with comorbidities, and often have cognitive or communication impairments. The Patient Reported Outcomes Initiative for Multiple Sclerosis (PROMS) has been launched to tackle this challenge for patients with this disease. Expectations are high because efforts to enable uptake of PROs could be greatly enhanced by a common strategic agenda, and PROMS' achievements could also influence clinical research in other subspecialties.

Although clinicians acknowledge the importance of PROs to facilitate understanding of treatment effects or compare treatment options, patients are frustrated that functional domains that matter most to them are often not addressed. Regulatory authorities recognise that current research outcomes (eg, the Expanded Disability Status Scale, relapse rate, and MRI features) do not fully capture the lives and experiences of people with multiple sclerosis; Healthcare Technology Assessment agencies aim to integrate the patient voice in coverage decisions; and pharmaceutical companies have acknowledged the importance of including PROs in the lifecycle management of experimental therapies. Practical issues include how to capture the pertinent data (eg, by use of technology), the need for a clear definition of which between-group differences and within-subject changes are clinically meaningful, and understanding of how domains of interest purportedly assessed by a PRO measure are affected by unrelated contextual factors (eg, how marital issues or depression might affect self-reported disease status).

In recognition of the need for a common strategic agenda and roadmap shared by all relevant stakeholders to tackle these issues and facilitate the uptake of PROs into decision-making processes, the PROMS initiative was born—a project aiming to provide a unified view on and maximise impact of patient input on the health, health-care, and quality of life of people affected by multiple sclerosis. The Multiple Sclerosis International Federation, the Italian Multiple Sclerosis Society, and the European Charcot Foundation launched PROMS on Sept 12, 2019, at the 35th Congress of the European Committee for Treatment and Research in Multiple Sclerosis, held in Stockholm, Sweden. The strategic priorities of PROMS are centred around the validation and development of PROs that matter most to people with multiple sclerosis; implementation and support of initiatives aimed at validating and harmonising PROs across cultures; and translation of standardised data into a performance measure that captures the results most important for improving long-term wellbeing.

The PROMS initiative aims to learn from best practices of other ongoing relevant initiatives. For example, the European Charcot Foundation has experience providing a joint approach to coordinate existing initiatives in multiple sclerosis (such as MS Brain Health, MS in the 21st Century, Neuro-Compass, and ParadigMS Foundation); and the MULTI-ACT project, launched in 2018, is facilitating a collaborative approach to develop brand new tools to assess the value of research in neurology from the patients' perspective—the impact of research in multiple sclerosis will be assessed as a first step. PROMS could also learn from established initiatives that focus on patients' priorities in neurological research. For instance, the James Lind Alliance has been facilitating partnerships between patients, carers, and clinicians to set research priorities since 2004. Also, a Dutch initiative with a similar ethos for patient advocacy in Parkinson's disease—ParkinsonNet, established in 2004—is trying to include patients in health-care decisions and make specialist-care choices easily available for all patients with the disease. The model has already begun to spread, with adjustments made for cultural and system-specific needs to enable implementation in Germany and the USA.

Several previous initiatives have faltered, in most cases due to the lack of appropriate infrastructure and shared means of aligning efforts and results. There is a need for a global approach, across countries, stakeholders, and disciplines. A goal to accelerate shared learning is by no means an easy one, but will be essential to maximise the potential benefits of patient involvement in neurological research. With PROMS planning to deliver results in July, 2022, this goal can hopefully begin to be realised soon. ■ *The Lancet Neurology*

For more on **PROMS** see https://www.msif.org/news/2019/09/12/global-initiative-places-the-patient-voice-front-and-centre-in-ms-research-and-care/

For more on the **ECF MS Initiative** see https://www.charcot-ms.org/research-initiatives/multi-stakeholder-initiatives

For more on **ECTRIMS 2019** see https://www.ectrims-congress.eu/2019.html

For more on **MS Brain Health** see https://www.msbrainhealth.org/

For more on **MS in the 21st Century** see *J Neurol* 2013; **260:** 462–69

For more on **Neuro-Compass** see https://www.neuro-compass.education/en-gb/home/

For more on the **ParadigMS Foundation** see http://paradigms.foundation/

For more on the **MULTI-ACT initiative** see https://www.multiact.eu

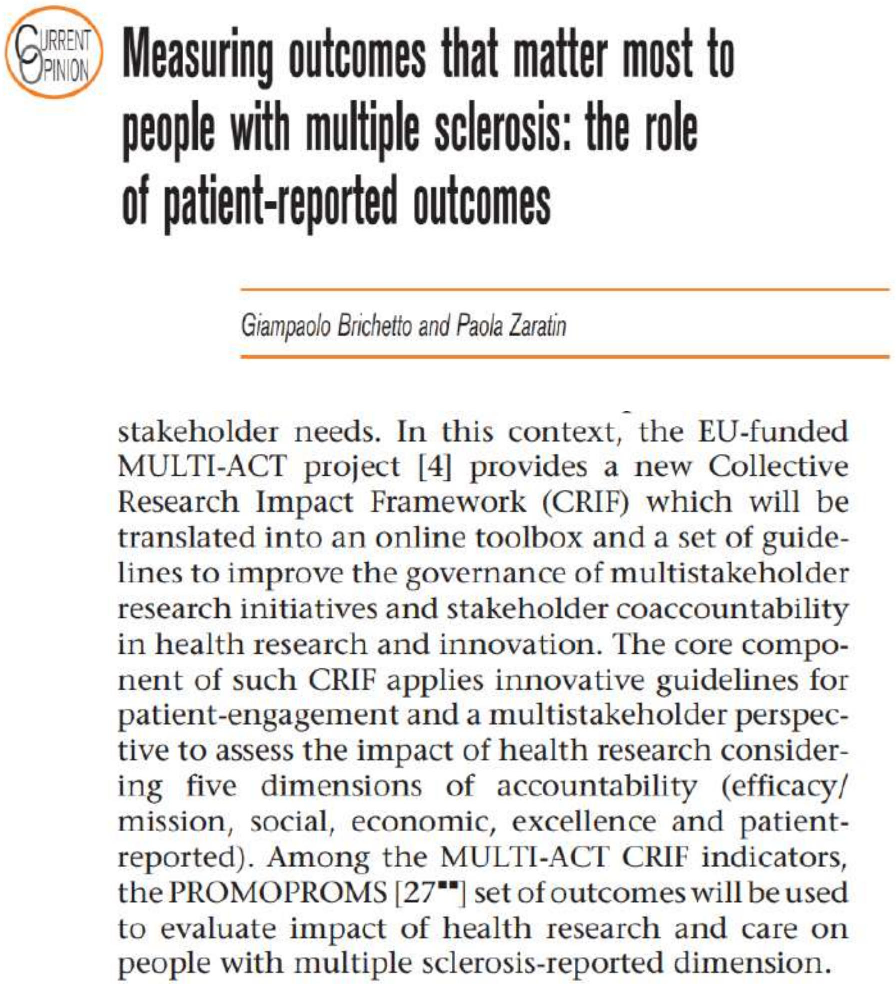
For more on the **James Lind Alliance** see http://www.jla.nihr.ac.uk/

For more on **ParkinsonNet** see **Editorial** *Lancet Neurol* 2014; **13:** 525 and http://www.parkinsonnet.info/media/15290577/nompen_on_the_move__2015__parkinsonnet_concept.pdf

www.thelancet.com/neurology **Vol 18 November 2019**

981

---



CURRENT OPINION

## Measuring outcomes that matter most to people with multiple sclerosis: the role of patient-reported outcomes

Giampaolo Brichetto and Paola Zaratin

stakeholder needs. In this context, the EU-funded MULTI-ACT project [4] provides a new Collective Research Impact Framework (CRIF) which will be translated into an online toolbox and a set of guidelines to improve the governance of multistakeholder research initiatives and stakeholder coaccountability in health research and innovation. The core component of such CRIF applies innovative guidelines for patient-engagement and a multistakeholder perspective to assess the impact of health research considering five dimensions of accountability (efficacy/mission, social, economic, excellence and patient-reported). Among the MULTI-ACT CRIF indicators, the PROMOPROMS [27••] set of outcomes will be used to evaluate impact of health research and care on people with multiple sclerosis-reported dimension.

SCIENCE AND SOCIETY

# Improve alignment of research policy and societal values

The EU promotes Responsible Research and Innovation in principle, but implementation leaves much to be desired

SCIENCE sciencemag.org 3 JULY 2020 • VOL 369 ISSUE 6499

- “Longer-lived investments are still needed for building a shared understanding and awareness of the relevance of responsibility in R&I among key stakeholder”
- The MULTI-ACT project represents a timely opportunity and an important reference for structuring a model of mission-oriented collective sustainability.
- COVID-19 pandemic calls for “RRI to shift from a cross-cutting issue to a strategic concern”

# Thank you!

**Multi-Act**
This project has received funding from the European Union’s Horizon 2020 Research and Innovation Programme under the Grant Agreement No. 787570