PROGRESSIVE MS ALLIANCE

More than hope. Progress.

FY 2020 Operational Plan

Mission, Who We Are and Values

Mission

To accelerate the development of effective treatments for people with progressive forms of multiple sclerosis to improve quality of life worldwide

Who We Are

The Alliance is an unprecedented global collaboration of MS organisations, researchers, health professionals, the pharmaceutical industry, companies, trusts, foundations, donors and people affected by progressive MS, working together to address the unmet needs of people with progressive MS—rallying the global community to find solutions. Our promise is more than hope, it is progress.

Our Values

- Collaboration we are stronger together, able to accomplish what no one could alone; we achieve the best results from integrating a range of perspectives, talents and experiences, inspiring people to make their best contributions
- **Be Bold** we pursue all promising paths, fearless in our search for solutions; we embrace opportunities for innovation and take calculated risks, recognizing that with failure comes valuable knowledge
- Excellence we identify and fund transformational research wherever it exists, focusing on life-changing solutions and achieving results; we are disciplined, agile and focused in all we do, working with rigor and catalyzing others
- **Inclusivity** we welcome all people with diverse expertise and experience, rigorously exchanging ideas and perspectives which builds trust, confidence and pride; the engagement and contributions of people affected by MS are essential
- Transparency we openly share information and knowledge on our progress, ensuring decision-making processes are known and people have what they need for understanding and doing their best work
- Acting with Urgency we work with purpose and relentless determination, knowing that over one million people living with progressive MS face uncertainty, losing ground each day

Impact and Priorities

Impact

- Approval and availability of new, effective treatments for progressive MS
- Improve quality of life for people with progressive MS worldwide

Priorities

- Understand Progression
 - Broadening and deepening knowledge about the biological mechanisms of progression
- Accelerate Clinical Trials
 - Developing tools for shorter, less costly clinical trials
- Enhance Wellbeing
 - Focusing the rehabilitation and wellness field to develop strategies and programs to improve quality of life

Focus within Priorities

At the heart of the current work of the Alliance are the 3 Collaborative Research Networks with a total investment of €12 million, our convening activities, and our focused engagement of persons with progressive MS to shape our agenda. All Networks are fully active, were at their midpoint in 2019 and are meeting their original milestones.

Initiatives are also being developed to address gaps in areas not supported by the Collaborative Network Awards. These initiatives, organized within our research priorities include:

Understand Progression

- -Ongoing Martino Collaborative Network
- -Ongoing Quintana Collaborative Network
- -New Data Sharing
- -New Experimental Medicine

Accelerate Clinical Trials

Ongoing – Arnold Collaborative Network

- -New -- Fluid Biomarkers
- –New Imaging and Functional Measures
- •Enhance Well-Being
- -New - Strategic Plan Development

Operational Plan

Priority Audiences

- Alliance members and MS organisations
- People affected by MS
- Donors

Other Key Audiences

- MS scientific research community
- Pharmaceutical and bio-technology companies with an interest in MS
- International corporations with an interest in MS
- Foundations and trusts with an interest in funding biomedical research related to neurological conditions, MS, collaborative research, basic/discovery research, chronic conditions, rare diseases and/or technological solutions to health issues

Strategies

- Raise Profile and Accelerate Progress
- Secure Resources and Globalize Research Funding.
- Inspire, Galvanize and Engage
- Deliver Operational Excellence

Strategy 1: Raise Profile and Accelerate Progress:

Objective 1. Collaborative Network Award Oversight

Initiatives:

- 1. Review progress under the Research Plan, to identify any problems or issues (including without limitation any anticipated delays) and to plan for the next quarter; and
- 2. Review any proposed adjustments to the Research Plan.
- 3. Document any actions agreed and record any decisions made (the staff leads will draft the action minutes and share with attendees for comment, before finalizing the action minutes)
- 4. The SSC to evaluate and discuss aspects related to continued business management: Intellectual Property considerations, Business Development and Commercialization and, Expert input into the Networks
- 5. SSC to make recommendation to Executive Committee for funds for drug development activities associated with Collaborative Networks and/or other drug development activities

Milestones: Quarterly reports from Networks

Impacts to revenue and direct expenses: €3 million in FY20 for awards and €400,000 for potential drug development activities

Owner: Doug Landsman with support from Lenka Yunk, Bruce Bebo and Sorrel Bickley

Objective 2. Disease Mechanism RFA: Invest in studies of underlying mechanisms that have the potential to discover new therapeutic targets and serve to re-engage the MS research community with the Alliance

Initiative: Develop RFA and review process

Milestones:

- RFA Release Date: Q1 FY20
- Informational call for Applicants: Q1 FY20
- Applications Due Q2 FY20
- Funding Decisions Q4 FY20
- Start date of projects Q4 FY20

Impacts to revenue and direct expenses: €750,000 in FY20 (total investment €1,500,000)

Owner: Doug Landsman and Lenka Yunk

Objective 3. Fluid Biomarkers: To develop and validate a treatment response biomarker. Focus on Serum Neurofilament light (SNfL) –critical mass of data emphasizes importance of validating its

utility as a tool for clinical trials in progressive MS.

Initiatives:

- 1. To measure outcome in phase II proof-of-concept trials of short duration. This effort will serve as a pathfinder for assessment of future candidate biomarkers
 - a. To predict future functional impairment/disability; and
 - b. To select patients for entry into Phase III trials

Milestones:

- Submit position paper for publication Q1-Q2 FY2020
- Present Implementation plan to SSC February 2020

Impacts to revenue and direct expenses: €350,000 in FY2020

Owner: Kathy Smith with support from Doug Landsman

Objective 4. Experimental Medicine Trials: To advance potentially impactful therapies while generating or supporting hypotheses about the basic biology of progressive MS

Initiatives:

- 1. Develop an experimental medicine trial protocol guideline Q1-4 FY19
- 2. Design RFA using the protocol and landscape analysis Q1-2 FY20
- 3. To utilize the Experimental Medicine Trials working group in an interactive review process for the RFA Q2-3 FY2020

Milestones:

- Submit position paper for publication Q1-Q2 FY2020
- Present Implementation plan to SSC February 2020

Impacts to revenue and direct expenses: €500,000 in FY19

Owner: Marco Salvetti and Susan Kohlhaas with support from Doug Landsman

Objective 5. Data Sharing: Enable the development of a unique high-quality database to understand the determinants of progression independent of relapse activity in MS

Initiatives:

- 1. Leverage investments from industry and the Collaborative Networks will further expand our understanding of progression and advance potentially impactful therapies.
- 2. The development of a high-quality database will help optimize clinical outcomes data (rederived), which could be used to identify and validate potential biomarkers of progression independent of relapse activity.
- 3. Initially this will be developed as a repository for placebo-arm clinical trials but could be expanded to include other relevant clinical data.

Milestones: Present implementation plan to Alliance leadership TBD

Impacts to revenue and direct expenses: €0 in FY19

Owner: Doug Landsman with support from Karen Lee, Pamela Kanellis and Shibi Belachew

Objective 6. Imaging and Functional Measures: Ensuring linkage and coordination across initiatives to identify relevant gaps and/or synergisms, including global MS Society portfolios; Alliance current initiatives; and other relevant initiatives such as Magnetic Resonance Imaging in MS

-MAGNIMS, North American Imaging in MS Consortium –NAIMS and the Italian Neuroimaging Network Initiative – INNI- MS visual initiative.

Initiatives:

- 1. Bring together expert working group to guide the strategy (Meetings, structure, etc.)
- 2. Develop imaging research programs

Milestones: Present implementation plan to Alliance leadership — FY20

Impacts to revenue and direct expenses: €25,000 in FY20

Owner: Paola Zaratin and Tim Coetzee

Objective 7. Enhance Wellbeing: Produce a comprehensive rehabilitation strategy that addresses symptoms, the broad research pipeline (mechanisms, clinical trials, implementation) and considers the variability in disease progression, in people with progressive MS.

Initiatives:

- 1. Build an implementation team with expertise in mechanisms, clinical trials, outcomes and implementation in the areas of motor function, cognition, fatigue, pain, comorbidities and resilience.
- 2. Create an outline and write a paper that provides strategies for researchers and clinicians in the wellness and rehabilitation fields.
- 3. Identify the gaps in the research literature and provide recommendations to scientists in the area of wellness and rehabilitation.
- 4. Share the gathered information with the Alliance Leadership and define next steps.

Milestones: Present implementation plan to Alliance leadership — February 2020

Impacts to revenue and direct expenses: €600,000 FY20

Owner: Kathy Zackowski with support from Doug Landsman

Objective 8: Candidate Prioritization

Initiatives:

- 1. Provide expert guidance on candidate lead/compound opportunities to investigate further. Identify lead and compound opportunities
- 2. Provide advice on how to work with Industry partners
- 3. Guide the Alliance on next steps of drug development.

Milestones:

- Form group Q1 FY20
- Convene first meeting Q2 FY20
- Develop guidance recommendations Q3 FY20

Owner: To be determined

Impacts to revenue and direct expenses: €100,000 in FY20

Objective 9: Industry Forum

Initiatives:

- 1. Plan and convene Industry Forum meeting
- 2. Serve as a convener to bring together industry perspectives and recommendations around candidate prioritization and other key issues affecting industry
- 3. Develop funding packages and proposals for Alliance initiative support
- 4. Engage biotech and other companies focused on drug development for people with progressive MS

Milestones: Host Industry Forum meeting, Milan, IT — February 2020

Impacts to revenue and direct expenses: €35,000 for Industry Forum expenses in FY20, anticipated income of €660,000 for membership fees

Owner: Shawna Golden, Kathy Smith, Paola Zaratin and Kate Daniels

Objective 10: MS Organization Portfolio Landscape Analysis

Initiatives:

- 1. Coordinate, update and compile national research portfolios
- 2. Create analysis and report

Milestones: Present update and analysis to Alliance leadership — February 2020

Impacts to revenue and direct expenses: In-kind support from Member Organizations

Owner: Doug Landsman, Tim Coetzee, Gabrielle Dati and Julia Morahan, with support from Cathy Carlson

Objective 11: Scientific Congresses and Scientific convening activities and meetings

Initiatives:

- Develop program and agenda for 2020 Scientific Congress Q1 and Q1 FY20. Convene Congress — June 2020
- 2. Convene SSC for Implementation Report and Prioritization Meeting February 2020

Milestones:

Implementation Report and Prioritization Meeting — February 2020

• Boston Congress — June 2020

Impacts to revenue and direct expenses: €400,000 in FY20 for Congress and €30,000 for Implementation meeting

Owner: Doug Landsman, Shawna Golden, Kate Daniels, Lenka Yunk, members of planning committees

Objective 12: Continue to integrate people affected by MS in Alliance initiatives and integrate people living with progressive MS in the Implementation Planning Teams

Initiatives:

- 1. Continue to engage and integrate people living with progressive MS in the SSC and Implementation Planning Teams
- 2. Leveraging the collaboration with MUTI-ACT, form the People Affected by Progressive MS Engagement Coordination Team to create principles that address potential policies and processes needed to measure impact of research and treatments on outcomes specific to patients living with progressive MS

Milestones:

- Form the People Affected by Progressive MS Engagement Coordination Team Q2 FY20
- Collaborate and provide feedback to the MULTI-ACT framework that aims to allow for effective cooperation of all relevant stakeholders in multi-stakeholder health research initiatives. — Q2-Q3 FY20
- Engagement Coordination team to contribute feedback toward a set of guidelines for Patient
 Engagement to be adopted by multi-stakeholder health research initiatives providing an evidencebased method for patients to most effectively contribute to research activities Q3-Q4 FY20
- Inform and provide feedback and perspectives to the development and execution of key Alliance scientific initiatives — Q4 FY20

Impacts to revenue and direct expenses:

- MULTI-ACT to provide staffing resources to support .83 of a Full Time Employee or equivalent of 2 people at .4 FTE (In Kind support from MULTI-ACT, Italian MS Society)
- Travel and expenses of committee members to attend 2 in-person meetings (€50,000 FY20)
- People Affected by MS Meeting Amsterdam meeting expenses (€10,000 FY20)
- Convening activity to bring together key stakeholders (other patient engagement initiatives, industry),
- Travel expenses and travel insurance (€97,500 FY21)

Owner: Paola Zaratin, Shawna Golden, Graham McReynolds and MULTI-ACT staff

Strategy 2: Secure Resources and Globalize Research Funding

Objective 1: Develop case statement, fundraising tools and funding packages for use by

Alliance members

Initiatives

- 1. Donor Engagement and Case Statement/Funding Packages Work Groups charged with responsibility for delivering on objective Ongoing through FY20
- 2. Year-long donor engagement plan and schedule completed Q1 FY20
- 3. Staff fundraising guide updated Q1 FY20
- 4. Case statement completed Q2 FY20
- 5. Targeted funding packages are developed and in use Q3 FY20

Milestones

- Annual calendar of donor engagement shared with all members Q1 FY20
- Funding packages available for use at Milken Global Conference Q3 FY20

Impacts to revenue and direct expenses: Increases ability of member organisations to meet and exceed commitments; expenses for professional writer

Owner: Graham McReynolds

Objective 2: Track, evaluate, leverage and support managing member and supporting member fundraising

Initiatives

- 1. Quarterly review and plan improvement by Donor Engagement Work Group for managing members and MSIF staff for supporting members Ongoing
- 2. Share campaign materials and member organization strategies Ongoing
- 3. Provide support on proposals, cultivation, stewardship and recognition Ongoing

Milestones

- Campaign materials shared with all managing members
- Proposal template distributed

Impacts to revenue and direct expenses: Expansion of donor pipeline

Owner: Graham McReynolds

Objective 3: Develop and implement plan for May 2nd-6th Milken Institute 2020 Global Conference to secure at least two seven figure donors

Initiatives:

- 1. Work group established with focus on major giving opportunities Q1 FY20
- 2. Donors identified and solicited to help offset sponsorship costs Q1-Q2 FY20
- 3. Donors identified and cultivated from multiple MS organizations for attendance Q1-Q3 FY20
- 4. Program and speakers identified and secured with Milken staff team— Q2 FY20
- 5. Off-site donor event plan developed and implemented Q1 FY20

Milestones

- 20+ donors identified and secured for event attendance
- Solicitations are made to best prospects following event

Impacts to revenue and direct expenses: New prospective major donors identified and engaged; expenses for donor engagement activities

Owner: Graham McReynolds

Objective 4: Support ongoing outreach and engagement of MSIF member organisations

Initiatives:

- 1. Plan for existing and prospective members updated with MSIF leadership including Peer Baneke, Luke Thomas, Victoria Gilbert and Anne Helme Q1 FY20
- 2. Managing member CEOs engaged in cultivation and stewardship Q1-Q4 FY20
- 3. Quarterly review of relationship management plan and identifying additional support needed Ongoing

Milestones

- CEOs are active in engaging member organizations
- One new member recruited and existing members continue their commitments

Impacts to revenue and direct expenses: secure existing funding and new contributors

Owner: Graham McReynolds

Objective 5: Ensure active engagement and deepened commitment of Patron, Champion and Friend members

Initiatives:

- 1. Launch and promote new donor membership levels Q1 FY20
- 2. Overall recognition and engagement plan developed and implemented resulting in an increased number of members Ongoing
- 3. Annual Progress Report provided to members Q3 FY20
- 4. Status of each member is reviewed and a renewal gift plan developed Ongoing

Milestones

- Increased number of members from multiple organizations
- Donors report feeling engaged and informed

Impacts to revenue and direct expenses: Expansion in membership increases both short-term and ongoing revenue

Owner: Graham McReynolds

Objective 6: Maximizes industry investment through targeted opportunities

Initiatives

- 1. Benefits for members and associate members are defined Q1 FY20
- 2. Video regarding the role of industry for use in companies is developed and distributed Q2 FY20
- 3. Interest areas of each company are identified and proposals are developed Q3 FY20

Milestones

- Video distributed
- New industry funding secured

Impact to revenue and expenses: New investment by industry; expense in video editing

Owner: Graham McReynolds and Shawna Golden

Strategy 3: Inspire, Galvanize and Engage:

Objective 1: Develop, implement and manage a relationship strategy plan and process for top relationships of the Alliance resulting in deepened engagement and increased commitment

Initiatives:

- 1. Top relationships of the Alliance are identified with an assigned relationship lead Q1 FY20
- 2. CRM tool used as appropriate Q1-Q4 FY20
- 3. Relationship plans implemented with leads Q2 FY20
- 4. Quarterly plan reviews by staff Q3 FY20

Milestones

- Relationship known and documented with an 'owner'
- Plan is implemented and reviewed

Impacts to revenue and direct expenses: risk to revenue and overall Alliance plan is minimized

Owner: Graham McReynolds

Objective 2: Develop, implement and continuously improve a comprehensive communications plan

Initiatives:

- 1. Communications plan is developed and implemented across all managing members with a focus on social video and website journey improvement Q1 FY20
- Content Work Group develops plan content and implements within each organization Ongoing
- 3. Targets and measures are developed, collected and analyzed for improvement Ongoing
- 4. Communications training for Alliance members that are affected by progressive MS Q1 FY20

Milestones

- Plan is known and executed in all managing member organizations
- People Affected by MS are trained, understand the communications strategy and feel confident in telling their story

Impacts to revenue and direct expenses: investments in identified communications assets **Owner:** Graham McReynolds

Objective 3: Expand Alliance positioning to clarify the problem being solved and the unique ability of the Alliance to solve; enhance core impact messaging

Initiatives:

- 1. Updated logo implemented and call to action developed Q1-Q2 FY20
- 2. Alliance positioning is expanded with expert consultation followed by executive committee approval Q2 FY20
- 3. Updated impact messaging approved and implemented Q2 FY20

Milestones

- Updated logo implemented
- Expanded positioning and enhanced impact messaging delivered at Milken Global Conference and Alliance Congress

Impacts to revenue and expenses: investment in case statement development

Owner: Graham McReynolds

Objective 4: Implement a year-long journey map for donors and people affected by MS with success measures

Initiatives:

- 1. Work Team reviews and approves journey map Q1 FY20
- 2. Implement, measure and improve map Ongoing
- 3. Develop and approve 2021 journey map Q4 FY20

Milestones

Journey map is used to implement plan and improve process in quarterly work team meetings

Impacts to revenue and expenses: investments in communications assets to support the mapped experiences

Owner: Graham McReynolds

Objective 5: Develop assets with a focus on video for increasing engagement in the Alliance and ensure their use among managing members

Initiatives:

- 1. A series of highly effective video assets developed and implemented by Content Work Group Ongoing
- 2. Social video plans developed, tested and measured Ongoing
- 3. Webcast plan developed and implemented Q2 FY20
- 4. Infographics developed for web and social use Q2 FY20
- 5. Alliance 'commercial' video plan distributed Q2 FY20
- 6. 2021 asset plan developed and approved Q4 FY20

Milestones

- · 'Commercial' to inspire and engage is broadly implemented and well received
- Infographics help tell the Alliance story more effectively

Impacts to revenue and expenses: investments in assets required

Owner: Graham McReynolds

Objective 6: Implement Alliance and Member website strategy and plan

Initiatives

- Establish new Alliance website architecture and user journey through Website Strategy and Plan Work Group — Q1 FY20
- 2. Develop and post streamlined content for site Q1 FY20
- 3. Develop criteria for member organization landing pages Q1 FY20
- 4. Launch 'new' site and improved member landing pages Q2 FY20
- 5. Develop and implement continuous improvement process Q2 FY20, Ongoing

Milestones

- Launch of new site and member landing pages Q2 FY20
- Increased site traffic to Alliance and as a result, increased traffic on member landing pages

Impact to revenue and expenses: Increased engagement on sites results in increased donor revenues; expenses for temporary web assistant and vendor work

Owner: Graham McReynolds

Strategy 4: Deliver Operational Excellence:

Objective 1: Manage the transfer and holding of funds raised and expenditures (research, research strategy development, grant review, management, fundraising etc.) to support the Alliance.

Initiatives:

- 1. Provide quarterly reports on expenditures to the Executive Committee.
- 2. Facilitate annual invoicing of Alliance members
- 3. Payment of Alliance scientific grants
- 4. Manage monthly expense reimbursements, accounts receivable and accounts payable

Milestones:

- Quarterly reports on expenditures to the Executive Committee Q1, Q2, Q3, Q4
- Manage monthly expense reimbursements, accounts receivable and accounts payable Ongoing

Impacts to revenue and direct expenses: In-kind support from Society finance team **Owner:** Shawna Golden, Kate Daniels and Doug Landsman

Objective 2: Develop and maintain annual budget, forecast and financial model for new investments

Initiatives:

1. Update financial model for new investments and changes to the funding model to assess funding needs every 6 months, report to Executive Committee (April and October) on assumptions, risks and mitigation plan

Milestones:

• Report to Executive Committee — April 2020 and October 2020

Impacts to revenue and direct expenses: in kind support from Society finance team

Owner: Shawna Golden

Objective 3: Evaluate and integrate project management tools and meeting material storage technology for the Alliance Staff team and Alliance committees and work teams

Initiatives:

- 1. With consultation from the Society technology team, evaluate and select online project management tools
- 2. With consultation from the Society technology team, evaluate and select meeting material storage technology
- 3. Manage the training, transfer of information and integration of tools for Alliance use

Milestones:

- Select tools Q2 FY20
- Integrate new tools Q3-Q4 FY20

Impacts to revenue and direct expenses: In-kind support from Society technology team

Owner: Kate Daniels

Objective 4: Manage membership agreements

Initiatives:

1. With consultation from Society legal counsel, manage updating, signing and execution of Alliance

member and Industry Forum membership agreements

Milestones:

• Update Managing Member MOUs and facilitate member signing — January 2020

Impacts to revenue and direct expenses: In-kind support from Society technology team

Owner: Shawna Golden

Objective 4: Coordinate the SSC Chair, Vice Chair and volunteer leadership succession planning

Initiatives:

- 1. Form and convene Chair and Vice Chair nominating committee
- 2. Develop succession Plan including transition timing and onboarding

Milestones:

• Present nominations for Chair, Vice Chair and plan for volunteer members — February 2020

Impacts to revenue and direct expenses: Staff time

Owner: Nominating Committee and Shawna Golden

FY20 Budget

	FY14-19 Total	FY20
Variances shown as Favorable (Unfavorable)	Actual	Budget
<u>Income</u>		
Australia	€ 1,385,865	€ 244,465
Belgium	201,250	
Canada	1,606,500	€ 280,500
Denmark	878,086	€ 123,000
Germany	250,000	
Italy	1,852,140	€ 320,000
The Netherlands	450,000	
UK	2,275,770	€ 440,000
USA	9,502,648	€ 2,700,000
Spain	354,643	€ 50,000
MSIF	44,532	€ 22,365
Norway	108,569	
France	491,500	€ 60,000
Ireland	30,094	
Sweden	53,000	
Finland	62,000	
Other MS Societies	800	
Scientific Professional Organizations	99,438	€ 50,000
Foundations	44,015	
Government		
Industry Forum (biomarker)		
Industry Forum - Project Specific Support		
Other Revenue (Online Donation, Misc Donation)	4,243	
Industry Forum - Membership Revenue	3,141,254	€ 660,000
Grants payable write off	157,178	
Interest income	40,801	
Total Contributions	€ 23,034,326	€ 4,950,330

	FY14-19 Total	FY20
Variances shown as Favorable (Unfavorable)	Actual	Budget
Expenses:		
Challenge Awards	€ 1,614,915	
Network Planning Awards	550,000	
Network Awards	6,195,327	€ 2,933,705
Understand Progression	10,000	€ 1,275,000
Accelerate Clinical Trials	10,000	€ 375,000
Enhance Well Being	10,000	€ 600,000
National portfolio research coodination activities		
Candidate Priortization Group		€ 100,000
Funds for drug development activities		€ 396,000
Regulatory Engagement: Policy and access work		
Implementation Planning Team Travel	50,000	
People w/ MS Travel (Implementation Planning Teams)	50,000	€ 157,500
Insurance/Risk Management		
Congresses	1,040,524	€ 400,000
Collaborative Network Investigator Meetings	400,000	
Scientific Steering Committee	1,700,372	€ 118,672
Executive Committee	901,365	€ 72,244
Communciations and Fundraising	480,272	€ 91,319
Industry Forum	462,501	€ 35,152
Staff salaries, benefits, travel expenses		€ 664,789
Transaction Gain/ (Loss)	116,653	
Total Expenses	€ 13,591,929	€ 7,219,381
Change in Net Assets		(€ 2,269,051)
Net Assets Beginning of Year		€ 9,442,397
Net Assets End of Year	€ 9,442,397	€ 7,173,346

Timeline