PML Consortium

EMA/FDA Workshop on PML

July 2011

PML Consortium and Funding

Vision and Mission

Vision

The Consortium aims to find methods to predict, prevent and treat PML.

Mission

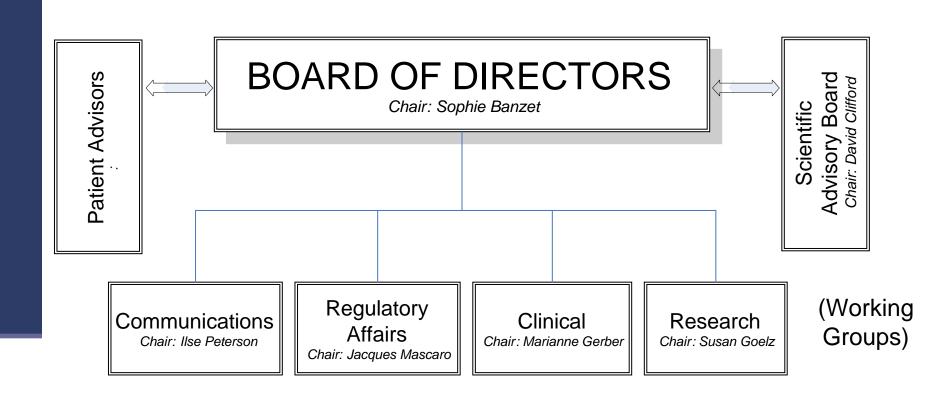
Perform research to reduce occurrence, morbidity and mortality of PML through:

- Multi-company, not-for-profit, collaborative approach
- Shared strategy, investment, data acquisition & analysis and communication
- Multi-year commitment from member organizations

Overview

- Vision and Mission
- Organization
- Funding structure
- Sustainability

PML Consortium



Secretariat (Drinker Biddle & Reath) provides legal (including antitrust), scientific, project management, and administrative support.

Member Companies

- Current Members
 - Biogen Idec
 - Bristol-Myers Squibb
 - Elan
 - Pfizer
 - Roche

Scientific Advisory Board

Remit

- Represent the interests of the recipients of the Consortium's work, including physicians and the scientific community;
- Provide feedback and advice on Consortium activities;
- Provide insight into advancements in the scientific and medical communities; and
- Assist the Consortium in disseminating information about PML, in collaboration with the Consortium's Working Groups.

Scientific Advisory Board

Composition

- David Clifford, Chair, Washington University School of Medicine
- Eugene Major, National Institutes of Health
- John Seeger, Harvard Medical School
- Alessandro Sette, La Jolla Institute of Allergy and Immunology
- Kenneth Tyler, University of Colorado School of Medicine
- Thomas Weber, University of Hamburg
- Monica Vinhas, EMA Observer

Patient Advisors

Collaborate with the Consortium to:

- Ensure the utility of the website through content review;
- Facilitate dissemination of knowledge about PML
- Assist expansion of network to include other entities focused on PML drug discovery

Key Accomplishments

Consortium established as a legal entity (December 2009)

2010-2011

- Agreement on funding
- Creation of Advisory Board
- Two new members (BMS and Pfizer)
- Clinical database in place
- Initiation of development of processes for standardization of data and sample collection, banking and storage
- Academic Collaborative Research Network grants, symposia and workshops
- Engagement with EMA, FDA and National MS Society

Near-Term Priorities

2011-2012

- Website
- Further Academic Collaborative Research Network grants, symposia and workshops
- Increase interface with patient association(s)
- Explore risk stratification, diagnostic and treatment options
- Recruit new partners

Funding

- Member companies have a sustained commitment to provide expertise, personnel and funding to advance the goals of the Consortium
- In accordance with the Consortium Bylaws, the budget is shared on equity across all member companies
- Decisions on PML activities
 - Consensus between companies
 - Prioritization of the activities in relation to the vision and mission of the consortium
 - Budgetary considerations

Funding & Considerations

- Current state: funding driven by current member companies
- Results needed to maintain member companies' engagement
- Awareness is critical and additional partners are important
- Challenges:
 - Individual corporate priorities
 - Long-term funding for the Consortium

Consortium Board of Directors

Biogen Idec

<u>Pfizer</u>

Teresa Compton, PhD Barry Ticho, MD, PhD

Claudio Carini, PhD Tom Kawabata, PhD

Bristol-Myers Squibb

Roche

Dolca Thomas, MD Steven Nadler, PhD

Sophie Banzet, MD (Chair) David Yocum, MD

<u>Elan</u>

Lori Taylor, PhD Nicki Vasquez, PhD (Vice Chair)

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