

# PML Consortium

EMA/FDA Workshop on PML July 2011

Session 8

Keeping Abreast of Progress for the Benefits of the Public  
Health

## *Role of the PML Consortium:*

# **Accelerating Progress in PML Research for the Benefit of Public Health**

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- The consortium is addressing a public health problem through innovation:
  - A new organizational model based on non-competitive collaboration focussing on risk
  - Innovative utilization of tools for communication and education
  - Transparency about activities, progress and accomplishments of Consortium
  - Sharing of best practices and approaches across companies and across therapeutic areas
  - Organization of transparent processes for data sharing to maximize utilization while ensuring patient privacy and scientific integrity

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## **Accelerating Progress in PML Research for the Benefit of Public Health**

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### **Key Stakeholders**

- Patients
- Healthcare professionals
- Regulators
- Advisors/academia and Researchers

### **Unique Utilization of Tools**

- Research funding
- Clinical database
- Scientific Advisory Board
- Patient advocacy groups
- Website
- Scientific conferences
- Regulatory meetings

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# **Accelerating Progress in PML Research for the Benefit of Public Health**

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### **Foster collaboration with communication and education**

- Research program and grants, workshops, publications
- Content identification for the PML Consortium website
- Consortium's PML Clinical Database may allow identification of broader trends across cases, including risk factors and variables that are associated with improved outcome
- Information with a regulatory dimension will require interaction with agencies
- Collaboration (e.g.: with regulators) to establish feasible clinical trial design and endpoints for potential PML treatments
- Availability of experts to work with regulators and other stakeholders on the need for specific guidance (e.g. PML case definition)
- Annual workshops to take stock of progress made