Considerations for Progressive Multifocal Leukoencephalopathy (PML) Clinical Trial Designs

Closing Remarks

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Workshop Summary

Background
Endpoints for PML clinical trials → Panel Discussion
PML Patient Perspectives
Selection of Control Groups → Panel Discussion
PML Clinical Trial Designs →Panel Discussion

- Speaker slides, transcripts, and recordings will be available on the meeting's webpage in the coming days

Thank you

- Speakers
- Panelists and Moderators
- PML survivors
- Workshop participants
- PML clinical research community
- FDA leadership and PML project supporters throughout the Agency
- CDER Public Meetings Team & Technical Support

FDA Resources

- **Rare Diseases: Common Issues in Drug Development Guidance for Industry. Draft Guidance. January 2019** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/rare-diseases-common-issues-drug-development-guidance-industry
- **Rare Diseases: Natural History Studies for Drug Development March 2019** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/rare-diseases-natural-history-studies-drug-development
- **FDA Orphan Drug Designation Program** https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products
- **FDA Orphan Product Grants Program** https://www.fda.gov/industry/developing-products-rare-diseases-conditions/orphan-products-grants-program
- **Rare Disease Cures Accelerator – Data and Analytics Platform (RDCA-DAP)** https://c-path.org/programs/rdca-dap/

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