



Pintad Response Criteria in
Lymphoma Working Group
AKA: PRoLoG Committee

Co-Chairs

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○ Purpose:

- To provide meaningful feedback to Working Group (WG) regarding the application and use of recognized response criteria in lymphoma clinical trials from PINTAD community of users.
- To create productive dialogue between WG, agency, industry and other interested parties in order to clarify, simplify and reduce misunderstandings, misinterpretations and misadministration of published criteria
- Provide a platform for future communication of response criteria



○ Background:

- Published Lymphoma response criteria have been vital in the standardization and implementation of response assessments. They resulted in improved patient evaluation, eliminating ambiguity, facilitating comparison across patients and studies and simplifying reporting to regulatory agencies
- Many response criteria are developing from more evidence-based support rather than expert opinion but not necessarily input from end users.
- Ambiguity still exists, publication errors can be found and often times real world application identifies inconsistencies and contradictions not anticipated at the time of development
- Providing an avenue to review, discuss and provide feedback to the appropriate WGs and other interested parties would be valuable



- **Proposal:**
 - Establish PRoLog Committee
 - Voluntary working group that will meet virtually to define scope, milestones and assignments
 - Gather relevant documents for review
 - Create a “share point” or wiki documents or other sharing platforms
 - Identify areas of “uncertainty” from an end-user point of view
 - Establish and define ambiguities, confusion, inconsistencies, etc.
 - Create draft documents
 - Addresses areas of “uncertainty”
 - Make preliminary recommendations
 - Obtain feedback and input from PINTAD membership
 - Including best practices
 - Seek PINTAD community for approval
 - Facilitate dialogue and correspondence with appropriate WGs & interested parties
 - Publish correspondence of interaction



- What we are *not* seeking to do:
 - Create criteria of our own
 - Be a substitute for the excellent work and efforts of established WGs
 - Pay people for their time for participation



○ Steps- proposed

- Call for volunteers – Ron Korn and Annette Schmid Nov 2018
- Create portal or wiki for access to documents
- Schedule first meeting to delineate scope of work Dec 2018
 - review committee, tasks, milestones and other activities
- Begin committee activity starting with Lugano (Cheson et al 2014) in Jan 2019
- First draft available beginning March 2019 for PINTAD comments
- Request for comments period ends April 2019
- PRoLoG comment review and final draft for approval early June 2019
- Communication with WGs August 2019
- Publication Submission 3rd quarter 2019

Thanks For Your Input!



What Do
You Think?



<https://mediavideo.blastingnews.com/p/4/2018/01/20/5e01d7c6-5ec6-40d1-9fbf-2910d0b94ad6.jpg>