**Agenda PINTAD**

March 31st, 2017, 11am EST

1. **Welcome**
2. **Dr Gregory Goldmacher,** Sr Director Translational Biomarker/ Merck presented an update on **assessment criteria for solid tumors in immunotherapies** (slides are available in this archive).

Following the presentation questions were raised around

* + - the impact of lesion heterogeneity on overall patient status determination, especially if in the non-target category. *Dr Goldmacher pointed out that changes in non-target lesions are integrated into the overall assessments similar to RECIST 1.1. What is novel is the differentiation between the continued worsening of the initial driver of the RECIST 1.1 (only worsening is required) versus the more stringent requirement of a RECIST 1.1 style progression confirmation if the initial lesions category (target, non-target or new lesion) remains stable or is improving while another category is clearly worsening. For example, an increase in non-target lesions that led to RECIST 1.1 progression (PD) at the prior timepoint only need to demonstrate further worsening to confirm the progression. If the prior timepoint RECIST 1.1 PD was driven by target lesions or new lesions, the non-target lesions would have to show RECIST 1.1 style unequivocal progression to confirm the progression. This is applied in similar fashion to a target lesion progression, where target lesions that triggered a RECIST 1.1 PD at the prior timepoint only have to demonstrate further worsening as expressed by ≥ 5mm increase in SOM (not an additional 20%). Dr Schwartz expanded that as the reason for progression is documented and monitored (including the following of new lesions as measurable or non-measurable) in iRECIST it allows for a deeper understanding of drivers of progression in different patient populations and disease settings. It may also provide valuable data for future modifications of the criteria.*
    - the need for central reads (the paper states that collection of scans is recommended but not independent review). *Drs Perrone and Schwartz acknowledged the importance of standardized interpretation of imaging that may be challenging in the context of new criteria and multi-site trials with numerous potential readers. RECIST 1.1 should continue to be used to define response based endpoints for late stage trials planned for marketing authorizations. For now data collection based on iRECIST is ongoing for testing and validating. A central review that controls the quality, centrally confirms outcomes and/ or supports the site interpretation is typically recommended. The statement in the paper is reflecting the fact that for now iRECIST will most likely be applied to exploratory endpoints where cost constraints may at times be considered to outweigh the quality concerns.*
* Drs Lawrence Schwartz and Andrea Perrone (both co-authors on the publication) pointed out that <http://www.eortc.org/recist/irecist/> is available as a resource. They encouraged all members to ask questions and share concerns via this website. It is anticipated that a FAQ section may be developed for the criteria over time.

1. **Ad-hoc topics**