

Silver Linings Playbook

The positive side of negative trials

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The positive side of negative trials

- What is responsible for negative trials and failed trials and how can we learn from them?
- Please consider some of the difficult questions that can have a tremendously deleterious effect on the ability of a trial to be successful

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The positive side of negative trials

- Was there an upper management or medical leadership change during the course of trial planning and execution?
 - How did it effect the results and what could have been done differently?
- How did shareholder concerns affect trial design?
 - Tendency for investors to be anxious about new innovative methodologies

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- Was there a rush to new countries (“having an IM in Kiev would be fun!”), and thus using assessments in a country for the first time.
 - new assessments may or may not perform well and a lot of new raters that will likely make a lot of mistakes at first during the learning curve
 - Maybe ok in early phases, but when large N’s are needed in phase 3 is when it usually happens

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The positive side of negative trials

- Should the study have been done in the first place? What forces may have set in motion a study that was doomed to fail?
 - Absence of internal sponsor subject matter expertise
 - Political decisions determining study design
 - The allure of false innovation
 - Unrealistic academic consultant cheerleaders
 - Follow AIFA and require a money back guarantee?
 - Job creation and maintenance
 - Inclusion of poorly performing sites with prestigious PI's
 - Lack of accountability; no consequences for a history of poor performance

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- Were there personnel involved in the trial that prevented it from being run effectively?
 - CROs, vendors, sites, sponsor

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- Did the study have at least one true champion?
 - Did the sponsor care about contributing to science?
 - Were the different teams involved in the trial held accountable by someone who was personally invested in the study being conducted well?

