ISBTC-FDA Meeting: Regulatory Breakout session

- **Conclusions:**
  - **FDA and NCI have already laid the groundwork for testing and approval of combination biologic therapies; is education the primary challenge?**
  - **Lack of investigator support by industry, lack of awareness of protection afforded by the FDA, and reticence to reveal IP even if protected are major regulatory hurdles to the development of novel combinations of biologic agents**

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Conclusions:

- NCI needs to devote resources to support re-certification of orphan biologics
- Would encourage that biologics without either pre-clinical evidence of anti-tumor effect in a relevant model or clinical evidence of activity (but appear active in combination) should not need testing alone
- Need ways to bring multi-component therapies quickly to early phase trials with NCI/FDA and Investigator cooperation

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Conclusions:

- Consider amending the phase 0 exploratory IND to allow more rapid screening of reagents that are biologic based on pharmacodynamic endpoints with actual clinically relevant doses of drugs