Potential issues?

- Collaboration between pharmaceutical companies?
- What method(s) to use to detect mutations?
  - Will a centralized assessment be necessary?
- Process associated with in vitro diagnostics under development?
  - Criteria for +/-?
  - Interactions with the FDA?

- Stage of disease/size of tumor?
- Multiple targets identified in the same tumor sample:
  - Which one to target? Which mutation is of concern/ is the driver?

- When multiple drugs are available for the same target/mutation, which drug to use?
  - Availability? Approved vs under development
  - The target profile of the drug? small molecules target more than one protein (e.g. multi-kinase inhibitors)
- Rare mutations?
- Hypothesis generating trials? Registration issues?
  - Potentially complicated trial design
  - Switching therapies, e.g. based on new mutations: Isolating the effect of a drug in the context of several drugs administered
  - Small number of patients

Next Step?