Industry Perspective

Elements of Informed Consent

- Consent must written in terms which are easily understandable, including at a minimum:
  - Reason for the study
  - What is unique about the study –
    - Novel technology
    - Improved features on established technology device or technology
    - Unique patient population qualifying for treatment
  - Any unique testing requirements or follow-up visits
  - Risks of study participation and if they differ from standard of care treatment for patient's condition
  - Alternative devices or treatments

Industry Perspective

Elements of Informed Consent

- Sponsors often conduct global trials which are governed by multiple regulatory agencies
- Sponsors have specific elements required in the informed consent, often resulting in a lengthy document
  - Pictures and simple tables are used to simplify content, when possible
- Each participating study institution may have unique requirements which require customization of the informed consent

Industry Perspective

Future Opportunities

- Integrating patient feedback in content and structure of informed consenting process
- Electronic and video informed consenting
- Additional supporting materials, like patient brochures, which cover the patient condition and what to expect with study participation, to help patients make an informed decision