

Industry Perspective

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Elements of Informed Consent

- Consent must be 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



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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



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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

