Data Reporting and Monitoring

Toxicity Criteria:

- Common Toxicity Criteria (CTC)
- CTC v2.0
- CTCAE v3.0

RECIST (Response Evaluation Criteria In Solid Tumors):

- RECIST FAQs and Article
- NIH-2819: Tumor Measurement/RECIST Criteria
- CTEP RECIST document
- WHO VS RECIST document

Regulatory:

- Food and Drug Administration (FDA)
- Good Clinical Practice in FDA-Regulated Clinical Trials
- Center for Biologics Evaluation and Research (CBER), FDA
- Center for Drug Evaluation and Research (CDER), FDA
- FDA MedWatch
- Office of Regulatory Affairs, FDA
- International Conference on Harmonization (ICH)

Sponsor:

- Cancer Therapy Evaluation Program (CTEP)
- Theradex
- Division of Cancer Prevention (DCP)