Module 6 Readings

Required:

The Metarrestin Clinical Trial Webpage on ClinicalTrials.Gov: Metarrestin (ML-246) in Subjects with Metastatic Solid Tumors.

Recommended:

These resources address clinical trials more broadly, and are as follows:

International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. (2000). *ICH Harmonized Tripartite Guideline. Choice of Control Group and Related Issues in Clinical Trials (E10)*.

International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use. (2016). *Guidelines for Good Clinical Practice E6(R2)*.

US Office of the Federal Register. (2018). *Electronic Code of Federal Regulations (ECFR) Part 46 — Protection of Human Subjects*.

United States Food and Drug Administration Clinical Trials Guidance Documents.