# **OCE Guidance Agenda**

# **New, Revised Draft and Immediately in Effect Guidances**

# **Planned for Publication in Calendar Year 2025[[1]](#footnote-2) (January 2025)**

(See the Good Guidance Practices (GGPs) regulation on this Web page or [21 CFR 10.115](https://ecfr.io/Title-21/se21.1.10_1115) for details about the Guidance Agenda)

**CATEGORY – Clinical/Medical**

* **Considerations for Including Tissue Biopsies in Clinical Trials[[2]](#footnote-3)**
* **Prevention and Treatment of Chemotherapy-Induced Peripheral Neuropathy: Developing Drug and Biological Products in Oncology2**
* **Development of Cancer Drugs for Use in Multiple Phases of Treatment – Determining the Contribution of Each Phase to Overall Effect**
* **Development of Cancer Drugs for Use in Novel Combination – Determining the Contribution of the Individual Drugs’ Effects**
* **Approaches to Assessment of Overall Survival in Oncology Clinical Trials**
* **Oncology Therapeutic Radiopharmaceuticals: Dosage Optimization During Clinical Development**
* **Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics (Revision)**
* **Myelodysplastic Syndromes: Developing Drug and Biological Products for Treatment**
* **Minimal Residual Disease and Complete Response in Multiple Myeloma: Use as Endpoints to Support Accelerated Approval**

*Note: Agenda items reflect guidances under development as of the date of this posting.*

1. OCE is not bound by this list of topics nor required to issue every guidance document on this list. We are not precluded from developing guidance documents on topics not on this list. [↑](#footnote-ref-2)
2. Draft guidance published on January 2025. [↑](#footnote-ref-3)