

# Considerations for Integrating Biosimilars Into a Practice



## • Safety and Efficacy Considerations

- Totality of Evidence
  - Analytical characterization
  - Pre-clinical studies
  - Pharmacology studies
  - Clinical trial design
- Clinical data
- Approved indications
- Extrapolation
- Immunogenicity
- Access to Medical Liaisons



## • Patient Considerations

- Comprehensive patient support programs & education



## • Economic Considerations

- Potential cost reductions
- Product characteristics
- Field reimbursement support



## • Manufacturer Considerations

- Quality manufacturing
- Medication availability
- History of shortages or recalls
- Supply chain security
  - Anti-counterfeit protection
- Handling practices
- Market sustainability



## • Practice Considerations

- Staff education supported by Medical Liaisons and Clinical Oncology Specialists
- Electronic Medical Record (EMR) protocols
- Computerized Provider Order Entry (CPOE)
- IT support for CPOE
- Pharmacovigilance protocols
  - Product naming & traceability
- Formulary management
- Available Stock Keeping Units (SKUs)
- Administration considerations
  - Differences in delivery devices

