Assessing the safety of biologics and biosimilars has many challenges, including:

– Some lack of direct relationship to “pharmacokinetics,” since PK concepts differ:
  • Role of direct PK of protein/peptide
  • Role of altered DNA or RNA and resulting proteins
  • If induced protein is the active agent….what is its t ½?

– For population safety, pharmacoepidemiology methods used for drugs are not always applicable
  • Detection of exposure (insurance codes)
  • Measuring exposure (kinetics, duration of effect vary
  • Dosing and methods of administration

• Risk management strategies may be difficult to design…and establish effectiveness