reduction in tumor size and number, as measured by the RECIST criteria, do not necessarily correlate with long-term survival to the cancer.

f. In choosing endpoints keep in mind the eventual goals of the clinical trial

For any given parameter collected during a clinical trial, the sponsor of the trial needs to determine if the parameter is properly used as an endpoint in the clinical trial, and whether the FDA will accept data on that particular parameter for:

- Regulatory approval of the drug;
- Including in the package insert for the drug; and
- Use in advertising to the public, that is, promotional claims.

A document used by pharmaceutical companies and called the Target Product Profile can be used to keep track of these goals (34,35).

[34] U.S. Dept. of Health and Human Services. Food and Drug Administration. Guidance for Industry. Target Product Profile – A Strategic Development Process Tool; March 2007;(25 pages).

[35] Lambert WJ. Considerations in developing a target product profile for parenteral pharmaceutical products. *AAPS PharmSciTech*. 2010;11:1476–1481.