

16.4 Individual Subject Data Listings

Data on file with the Sponsor.

Once filed by Sponsor with regulatory agency, section includes:

- Data tabulations
- Data tabulations datasets
- Data definitions
- Annotated case report form
- Data listing
- Data listing datasets
- Data definitions
- Annotated case report form
- Analysis datasets
- Analysis datasets
- Analysis programs
- Data definitions
- Annotated case report form
- Subject profiles
- IND safety reports