**TABLE 25.3** Example of Questions for Patients With Poorly Written Questions (Left) and Adequately Written Questions (Right)

| | Poor Writing | Better Writing |
|---|---|---|
| Avoid double negatives | Is the patient currently not taking asthma medication? ☐Y ☐N | Is the patient currently taking asthma medication? ☐Y ☐N |
| Specify time points | How would you rate your pain? ☐severe ☐mild | How would you rate your pain since your last visit? ☐severe ☐mild |
| Avoid two questions in one sentence | Were answers 28–32 reviewed by the nutritionist and was the patient eligible? ☐Y ☐N | Were answers 28–32 reviewed by the nutritionists? ☐Y ☐N |

clinical trials. Moon (302) details the content and appearance of a typical CRF used for clinical trials. Some CRFs may capture only AEs occurring at a given point in time, while other CRFs may be designed to capture cumulative information on AEs. An example of a poor CRF may contain fields for inputting WBC counts, where the field looks like this:

Neutrophils _____; Lymphocytes _____.

In contrast, a high-quality CRF will include the unit, and the field will look like this:
Neutrophils (cells/mL blood) _____;
Lymphocytes (cells/mL blood) _____.

CRFs should avoid double negatives, and should specify time points where appropriate, and should avoid lumping more than one question in a single sentence. This advice for a bad CRF and a good CRF is shown below (Table 25.3) (303).

Ene-Iordache et al. (304) describe issues relating to electronic CRFs, such as the requirement for the data-entry person to add an electronic signature, and the issue of the audit trail. Moreover, Headlee (305) teaches that CRFs may be designed in parallel with the writing of the Clinical Study Protocol, and that the form should include check boxes to capture AEs expected from the drug of interest, such as neurological AEs. Also, this author recommends using check boxes instead of spaces for writing, where appropriate, to increase the efficiency of filling, and the legibility, of the forms.

## e. Adverse Events—Capturing, Transmitting, and Evaluating Data on Adverse Events

The following diagrams illustrate the overall processes used for capturing, evaluating, and

[302]Moon KK. Techniques for designing case report forms in clinical trials. ScianNews 2006;9:1 (7 pp.).

[303]NHMRC Clinical Trials Centre, University of Sydney. Outreach. An Australian initiative to support clinical trials; September 2009. 2 pp.

[304]Ene-Iordache B, Carminati S, Antiga L, et al. Developing regulatory-compliant electronic case report forms for clinical trials: experience with the demand trial. J. Am. Med. Inform. Assoc. 2009;16:404–8.

[305]Headlee D. The paper trail: CRFs, source documents and data collection tools. SoCRA Source; May 2004;30 (4 pp.).