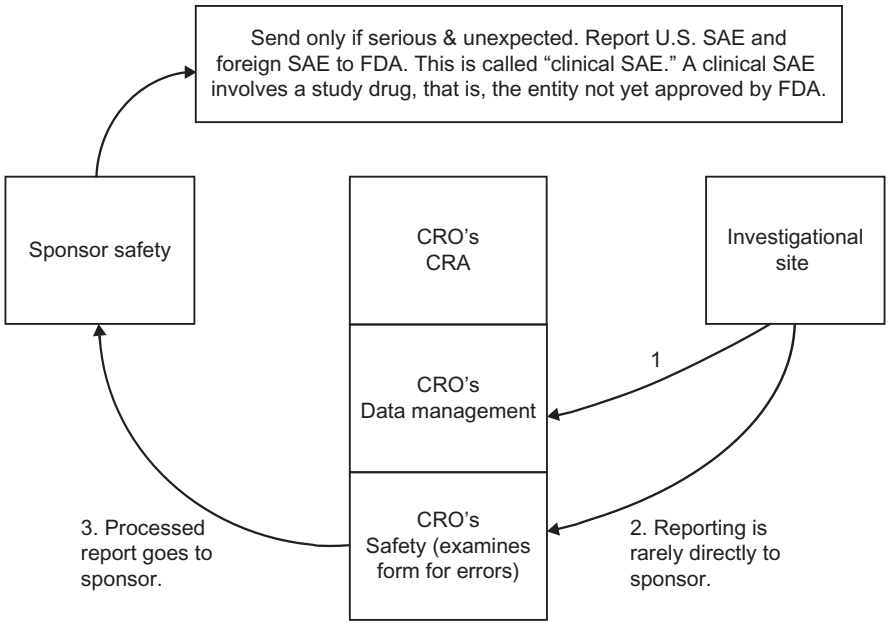

Figure 24.4 Initial report of SAE (situation where there is a CRO)

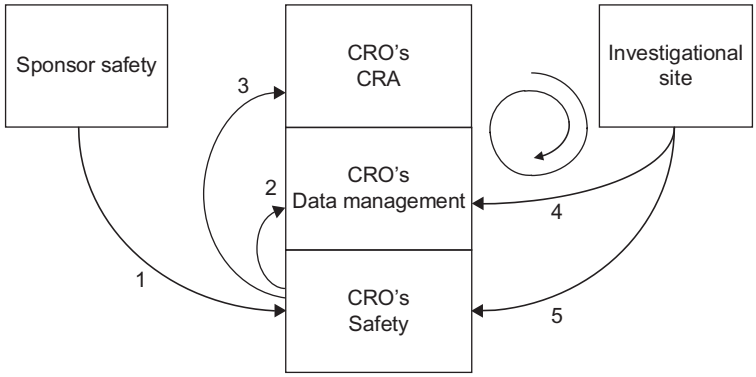

Figure 24.5 Follow-up report of SAE (situation where there is a CRO). Follow-up of an AE involves tracking down any missing data. The sponsor's safety director initiates this follow-up, but is not involved in subsequent steps. After the initial few steps, shown above, what occurs is a reiterative process involving three parties, where the CRO's CRA and the CRO's data management personnel contact the investigational site to make certain that all information for the case report form is filled out. The reiterative process is shown by the spiral

This summarizes the information set forth above from 21 CFR 32. First, it states that the investigator can use a special form (MedWatch Form 3500A) to submit the report. A similar form, MedWatch Form 3500, is reproduced in Fig. 24.6. Second, it states that FDA is only interested in receiving information about AEs that are serious