Table 31.3 (Continued)

IND safety reports
Plasma protein binding study reports
Hepatic metabolism and drug interaction studies
Human pharmacokinetic (PK) studies
Healthy subject PK and initial tolerability study reports
Patient PK and initial tolerability study reports
Reports of efficacy and safety studies
Integrated summary of safety report
Integrated summary of efficacy report

[a]http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163175.pdf (downloaded November 23, 2010).

An example is where the sponsor cannot collect information from an outside agency, unless the sponsor first approves of the clinical trial – but where the sponsor cannot approve of the trial, unless it first gets the information from the agency. Steensma (67) provides examples of circular mismatch in clinical trials, where changes in the Clinical Study Protocol, "can upset trial development homeostasis, creating endless loops or Catch-22s that then require special intervention to resolve. Committee A may need the approval of Committee B to move a protocol forward to Committee C, but Committee B may be silent because it is waiting on something from Committee A… some protocols have been delayed because study sponsors are reluctant to sign contracts until IRBs approve the protocol, yet some IRBs have been hesitant to approve protocols until contract language is agreed."

The following lists most of the offices or agencies that need to cooperate with each other, and that need to be coordinated, during a typical clinical trial:

- Principal investigators
- Sponsor
- Clinical trials office
- Regulatory staff
- Institutional review board
- Scientific review committee
- Contracts and grants office
- Division chair
- Department head
- Core medical team
- Secondary clinical research center
- Compliance office
- Director, medical affairs/oncology administration

[67] Steensma DP. The ordinary miracle of cancer clinical trials. *J Clin Oncol*. 2009;27:1737–1739.