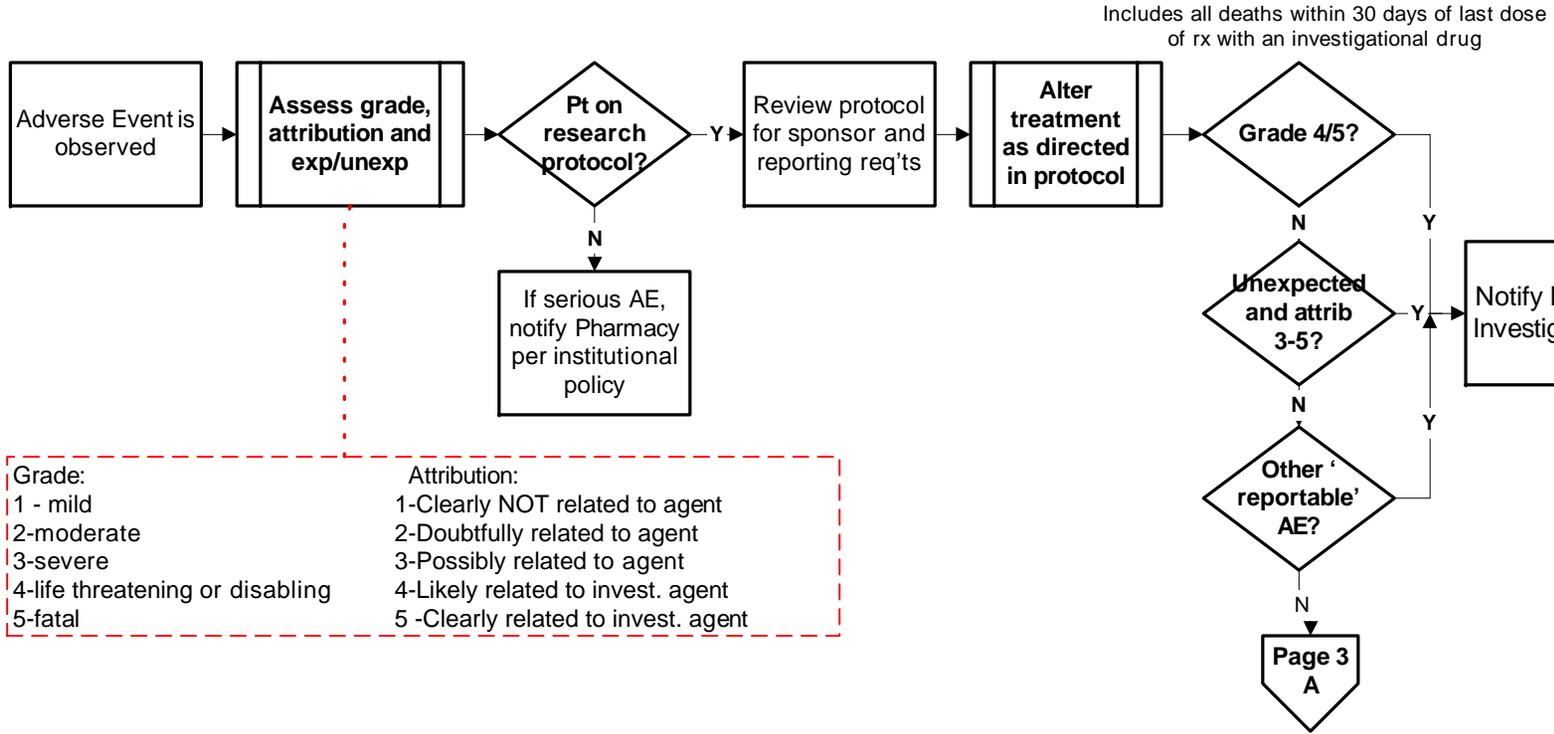


Identifying and Reporting of Adverse Events_Current Process

Treating Physician or Nurse

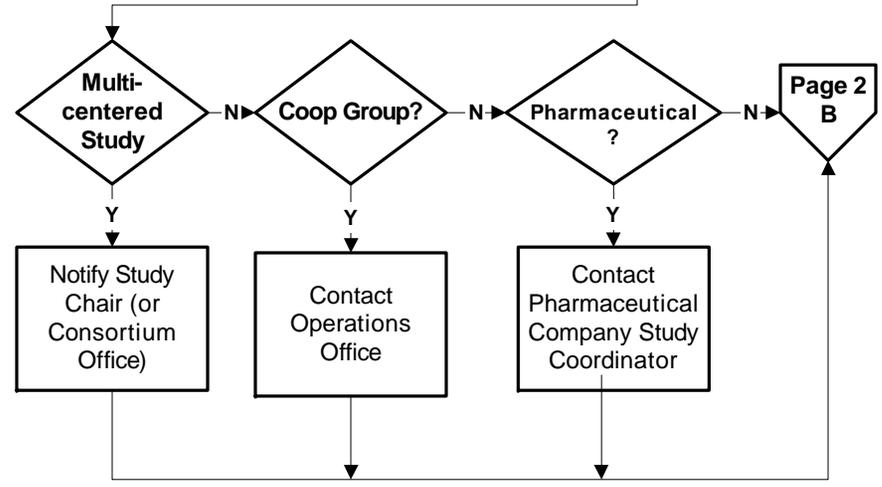


- | | |
|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Grade:
1 - mild
2-moderate
3-severe
4-life threatening or disabling
5-fatal | Attribution:
1-Clearly NOT related to agent
2-Doubtfully related to agent
3-Possibly related to agent
4-Likely related to invest. agent
5 -Clearly related to invest. agent |
|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

These are general guidelines. The protocol should be consulted for reporting requirements.

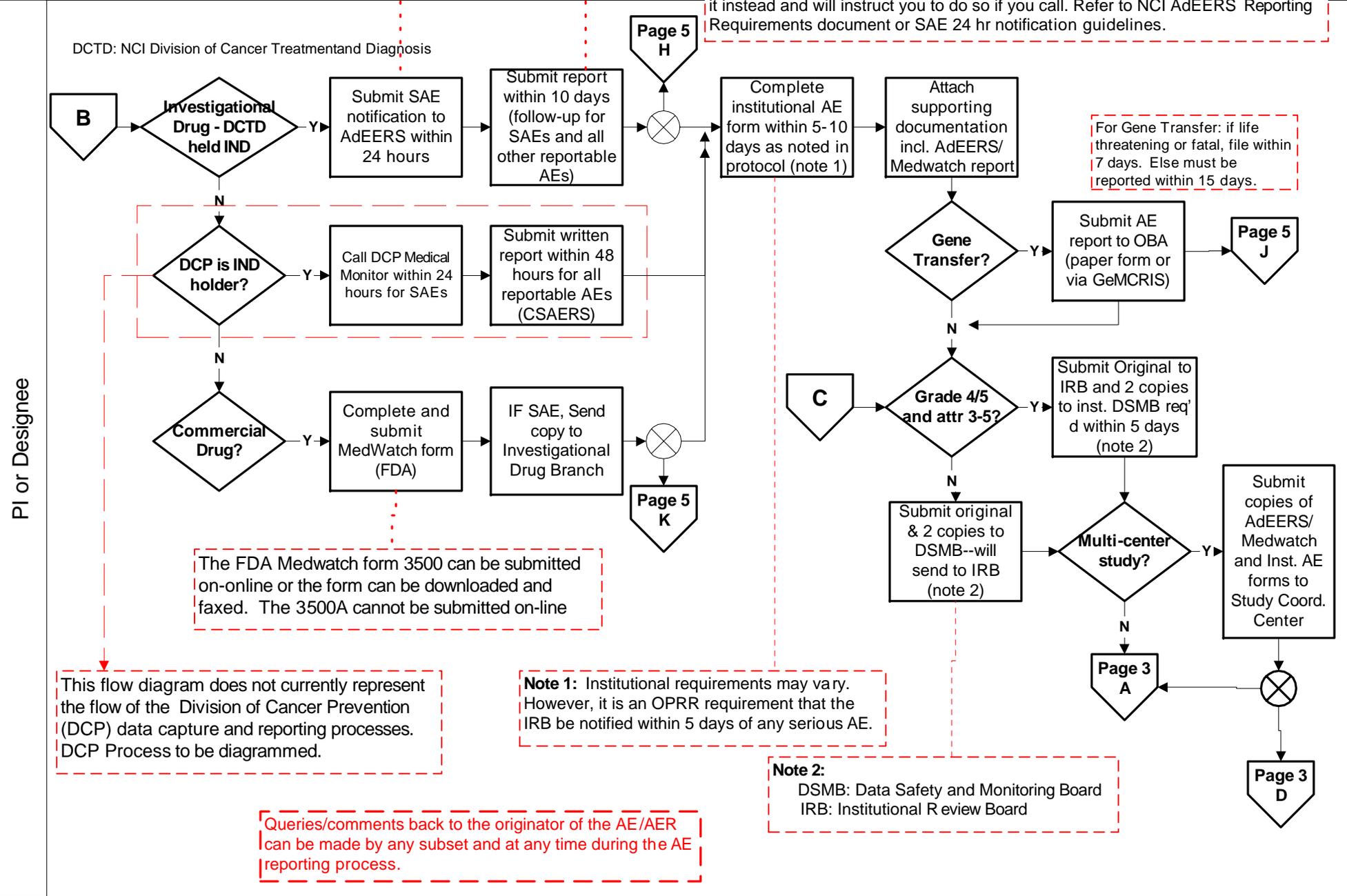
PI or Designee

Queries/comments back to the originator of the AE/AER can be made by any subset and at any time during the AE reporting process.

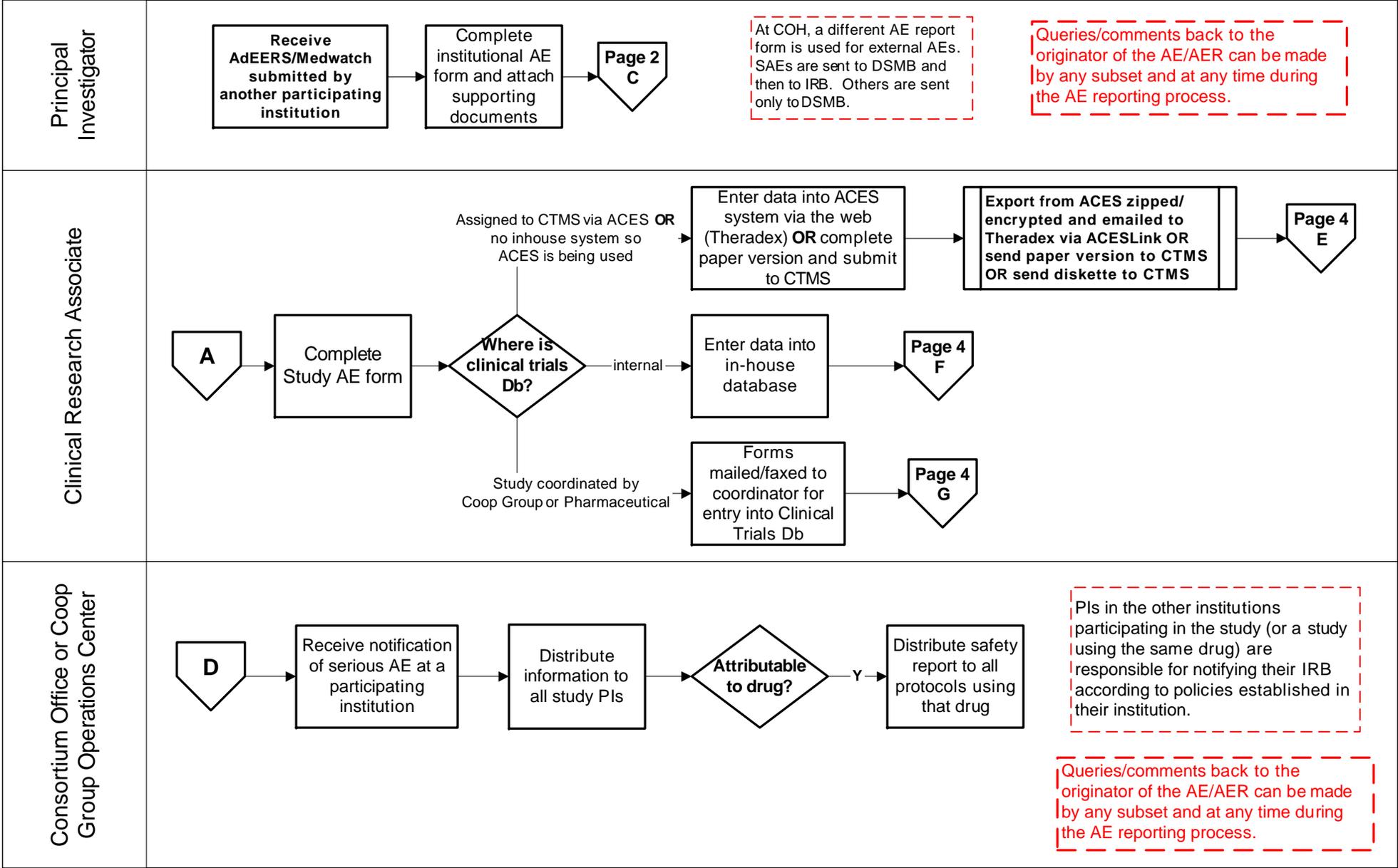


Identifying and Reporting of Adverse Events_Current Process (page 2)

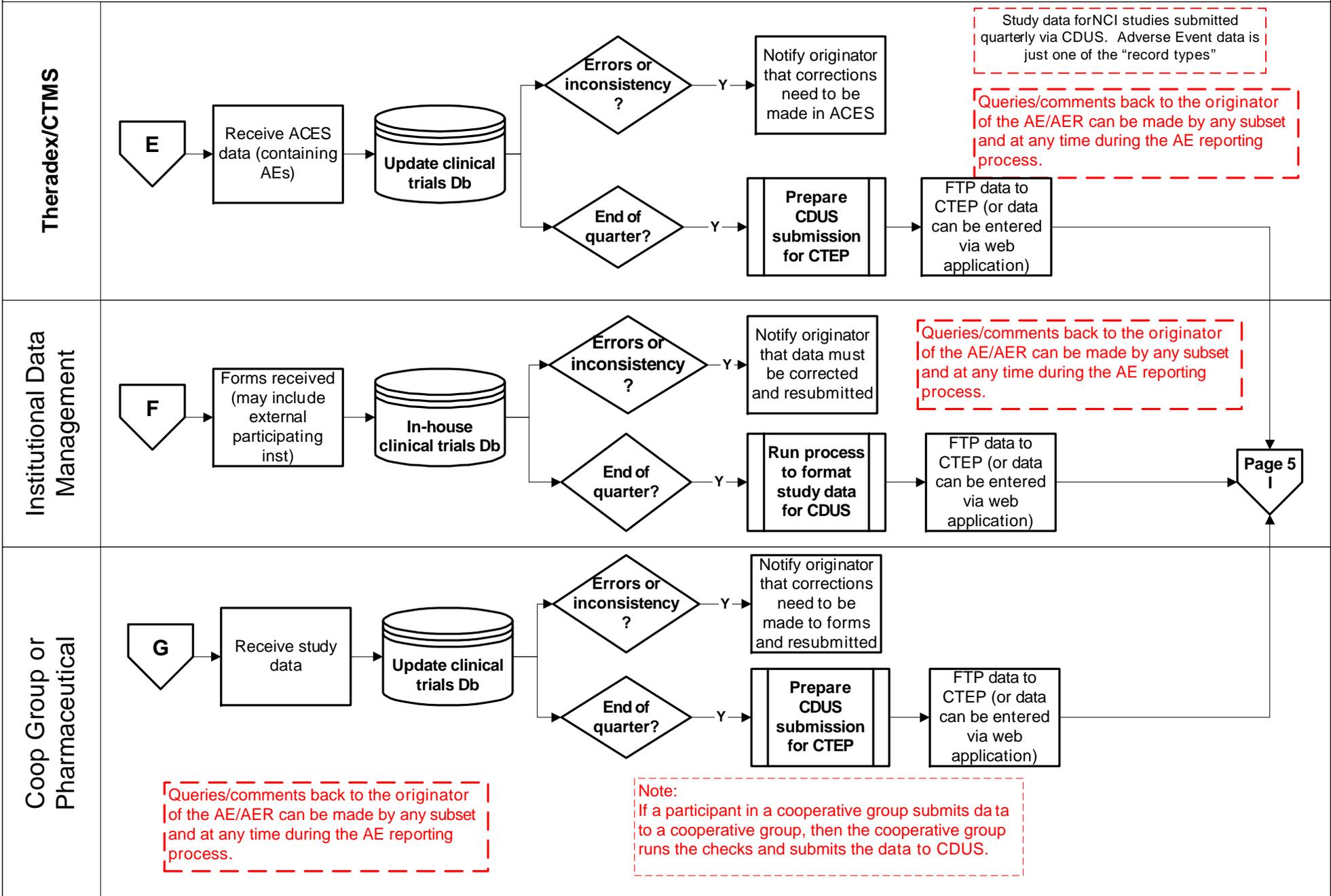
In the past, it was necessary to call IDB within 24 hours (this still appears in many protocols). Since AdEERS is now available on-line, the NCI requires that you use it instead and will instruct you to do so if you call. Refer to NCI AdEERS Reporting Requirements document or SAE 24 hr notification guidelines.



Identifying and Reporting of Adverse Events_Current Process (page 3)



Identifying and Reporting of Adverse Events_Current Process (page 4)



Identifying and Reporting of Adverse Events_Current Process (page 5)

