Timeline	FDA	Industry
-12 to -10 months		● Initiate overall plan
-9 months	● Identify need for meeting - topic, issues, product list ● Notify sponsor ● Identify current and prospective SGEs ● Data/literature review	● Teams begin work: - NDA Review Response Team (NRR) - Core AC Preparation Team (CAP) - Administrative Working Group (AWG)
-3 months	● Draft agenda ● Identify speakers ● Data/literature review ● FEDERAL REGISTER notice	● Teams continue work ● Hotel accommodations/meeting rooms • Mock Advisory Committee meeting
-2 months	● Screen current and newly appointed SGEs for conflict of interest	● Outline of briefing document to FDA
-1 month	● Background package to ACS ● Practice presentations ● Refine questions for AC	● Final briefing document to FDA ● Review of FDA briefing document ● Finalize presentations
-1 week	● Practice presentations	● Set-up in hotel ● Final rehearsals
-2 to -1 day	● Final questions to ACS/sponsor ● Briefing materials posted on the web	● Minor modifications to address specific questions (redraft virtually impossible)
AC/AdCom MEETING		
Post-meeting	● Presentations and briefing documents posted on website ● Transcript reviewed and posted ● Debrief/Decision	● External relations ● Review of outcome/next steps • Debrief meeting and post-mortem of process