Figure 1. Academic approach to Clinical Trial Design. The sequential steps involved in clinical trial development and execution are detailed. Blue ovals represent internal planning steps, whereas gray rectangles represent multisite planning steps, and green rhomboids represent regulatory steps. Points of intersection between this diagram and those in Figure 2 are indicated by using bold for the critical words in the text. *CDER may request a change with or without putting a “hold” on the study; CDRH may approve or disapprove the study. A full color version of this figure is available at the Pediatric RESEARCH journal online, as well as online at the ASPN website (see text for details).