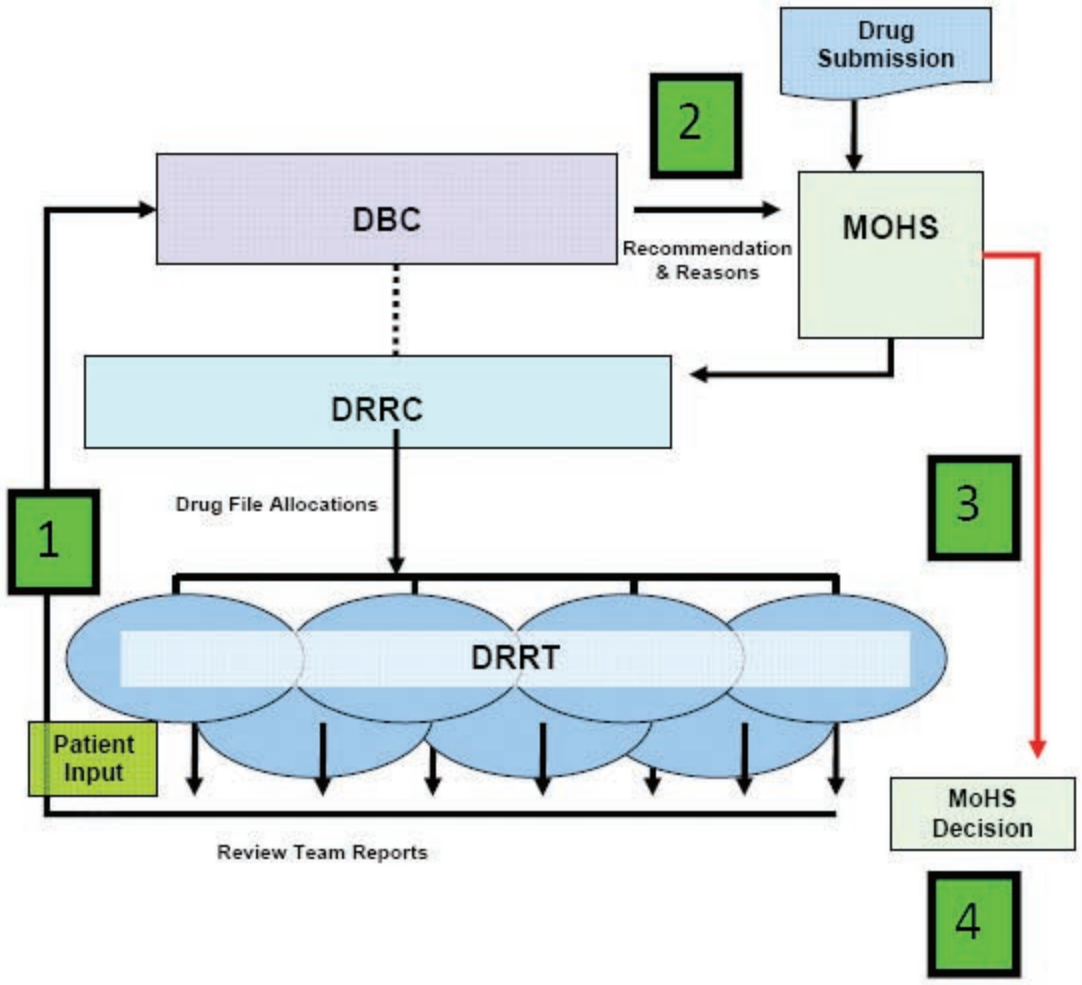
Sponsor Engagement



1 **Pre-DBC:** Sponsor may review DRRT reports and submit written DRRT report comments for DBC

2 **Post-DBC:** Sponsor provided embargoed DBC Recommendation & Reasons

→ Sponsor may file request for reconsideration based on grounds that either: (1) recommendation is not supported by evidence reviewed by DBC, and (2) DBC did not follow proper process.

3 **Pre-MoHS Decision:** Sponsor may engage (submit written statement and/or meet) with MoHS before decision / implementation

4 **Post-MoHS Decision:**

→ Sponsor may file resubmission if new information addresses reasons for decision (to CDR if CDR submission)

Applies only to drug submissions made after March 01, 2010