

## Singh, Joan

---

**From:** Barton, Joan  
**Sent:** Wednesday, December 06, 2000 7:13 PM  
**To:** Tiseo, Paul; Flicker, Charles; Howard, Joan; Wu, Jane; Cobles, Carlos  
**Subject:** CIT-MD-18 Study Drug



CIT-MD-18 Drug  
Problem doc

Dear All

Attached is a table showing which patients were randomized when the problem was discovered that the study drug was unblinded. A total of 6 Adolescents and 3 children had already been randomized.

Please let me know if this will alter the total number of child or adolescent patients to be randomized for this trial.

Thanks,  
Joan

**CIT-MD-18 - Study Drug Packaging Error  
Site Tracking – 3/1/00**

| Investigator | Randomized Patients                          | Screened Patients                                     |
|--------------|--|---|
| Apter        | None   | Screened one pt. – on placebo 6 days – On Hold        |
| Busner       | 3 Adolescents 505, 506, 507<br>1 Child 105   | Have 3 screens planned – will do only KSADS-PL & Labs |
| Dowben       | None   | None  |
| Ferguson     | None   | None  |
| Grob         | None   | 1 Screen Fail   |
| Harmon       | 1 Adolescent 509                             | 1 – Did Partial Screening – No Placebo Rx             |
| Holland      | None   | 1 Screened – Put On Hold                              |
| Preskorn     | None   | None  |
| Pumeriega    | None   | None  |
| Riesenberg   | None   | None  |
| Robb         | None   | 1 in Screening – advised not to randomize             |
| Stevens      | None   | 1 Screen Fail   |
| Wagner       | 2 Adolescent 513, 514<br>2 Children 113, 114 |   |

Urgent Fax Sent to Sites on 3/2/00 explaining problem and need to return randomized drug.

Kahn and Hendren Initations Pending - No Drug Shipped

Findling, Pfeffer, Silva, Weller – IRB Approval Pending - No Drug Shipped

Beckett, Goodman, Hassman – sites added at a later date