

MTN 001 Protocol Team Meeting
MTN Annual Meeting
March 17, 2010



Case Western Reserve/University Hospitals
Clinical Research Site

MTN001 Participant Retention

Robert Bucklew, Outreach Coordinator

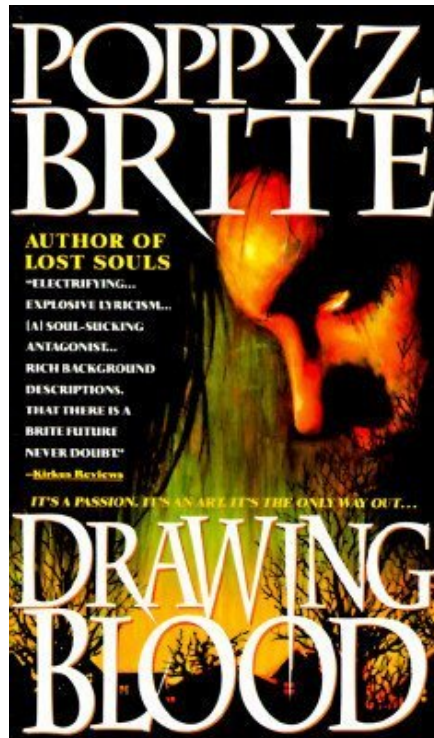
Early terminations: The Cleveland Six



1. withdrew consent and terminated early from the study (after her first study period) due to **poor venous access** which prevented collection of required PK specimens
2. withdrew consent and terminated early from the study (after her Enrollment Visit), stating **she did not use any study product** and did not wish to use it
3. withdrew consent and terminated early from the study (after her Week 3 Visit), stating that she "**wanted to conceive soon**"
4. withdrew consent and terminated early from the study (at her Week 3 Visit) , stating "**she did not want to take study drug**"
5. withdrew consent and terminated early for the study (after her Enrollment Visit) stating "**she no longer wants to participate.**"
6. withdrew consent and terminated early from the study (after her Enrollment Visit) stating that she thought the study "**was too invasive**"

Participant No. 1

1. withdrew consent and terminated early from the study (after her first study period) due to **poor venous access** which prevented collection of required PK specimens



Site response: During screening process, participants are checked for venous access for PK visits by Screening nurse and another nurse/doctor.



5 participant motivated
early terminations

Two groups:

Participants 2-5

Participant 6

Participant 6: Very difficult gynecological examination during enrollment visit

Participants 2-5: Came as “surprises” that participants did not want to continue

Common characteristics

- Terminated early – all terminated at week 3 visit or before
 - Three terminated soon after enrollment visit
 - Two prior to week three visit

5 participant motivated terminations: continued

No common recruitment methods/venues:

2 paid advertisement

1 Craig's List

1 friend referral

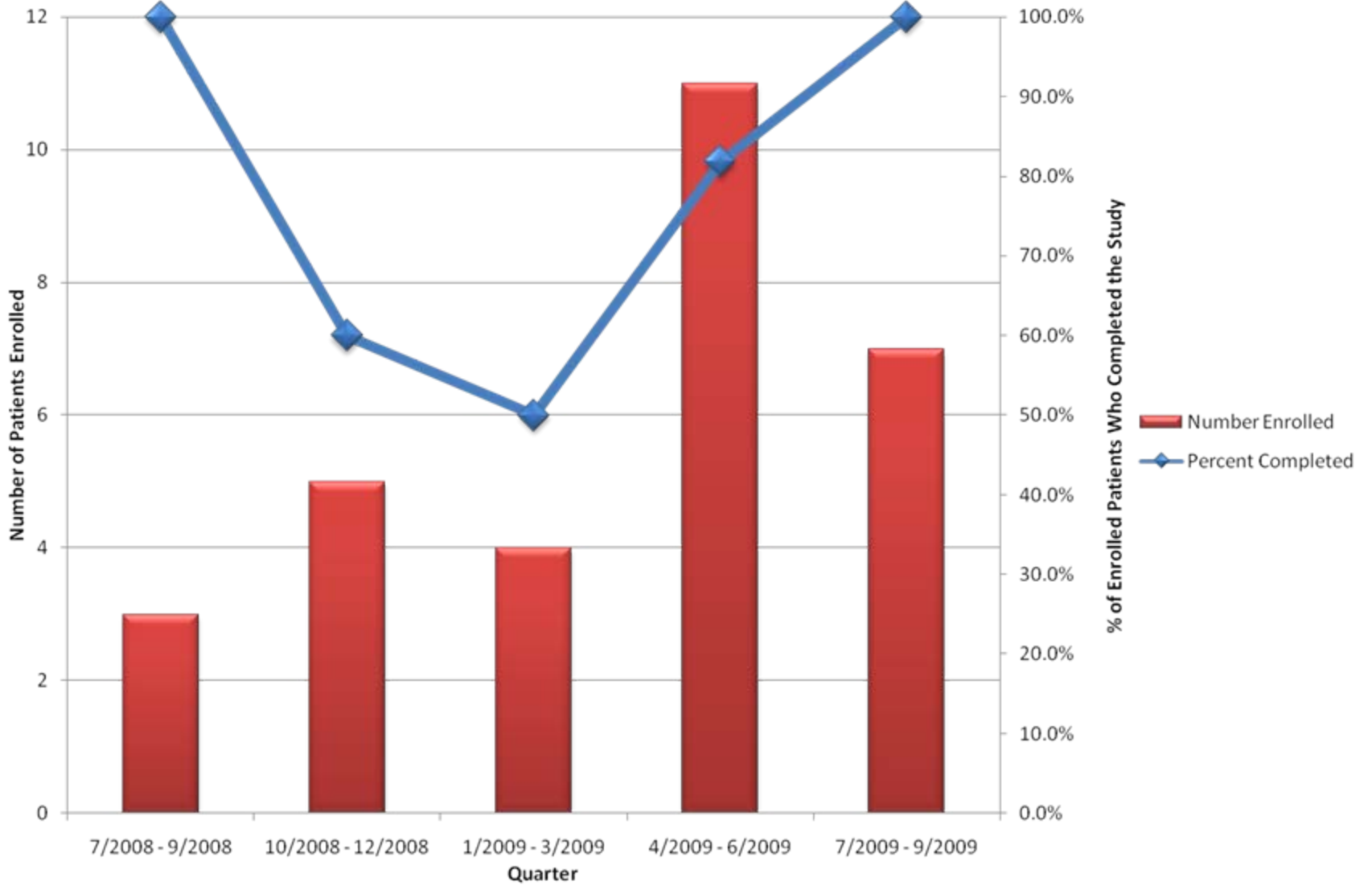
1 flyer

Randomized to products:

2 Oral

1 Gel/Oral

1 Gel



Summary

- **Unit changed procedures to assure adequate venous access during screening process**
- **Pre-screening and screening procedures remained the same, however emphasis**
 - **on importance of completion of trial**
 - **lack of hesitancy to take product**
- **Unit's retention rate improved over course of trial**

I'd like to
finish by
weakening
my case.



Questions
&
Answers