

Questions

- Should patients be PROHIBITED from participating in EAP if they have no other active (and tolerated) drugs to use with the new drug?
- If yes, then should FDA not allow even single patient INDs for such patients?
- If no, should patients be EXCLUDED from active controlled phase 3 trials (e.g., new integrase vs old integrase) if they have a PSS/OSS score = 0?
- Should excluded clinical trials patients be enrolled in EAP?