



F.No.16-16/2020 DD (PS).
Government of Pakistan
Drug Regulatory Authority of Pakistan
Pharmacy Services Division

Islamabad, the 3rd December 2020.

“SAY NO TO CORRUPTION”

✓
Dr Rizwana Chaudhry,
Head of Translational Research Department,
Shifa Tamee e Millat University,
Rawalpindi.

Subject: APPLICATION FOR A RANDOMIZED TRIAL TO ASSESS THE PHARMACOKINETICS AND PHARMACODYNAMICS OF INTRAMASCULAR, INTRAVENOUS AND ORAL ADMINISTRATION OF TRANEXAMIC ACID IN WOMEN GIVING BIRTH BY CAESAREAN SECTION.

This is with reference to your application received for approval from DRAP to conduct the WOMAN-Pharmaco TXA trial in Pakistan. It is informed that the CSC after discussion has decided the case in its 16th meeting held on 27th November 2020.

2. Decision of 16th CSC meeting:

Dr. Rizwana Chaudhri (Supervisor) and Dr Haleema Shakur -Still (Professor Global Health CT, London School Hygiene and Tropical Medicines) explained the case before the CSC and after detailed deliberation following decisions were taken with majority of votes;

- *The Dr. Rizwana Chaudhri and Dr Haleema Shakur -Still will submit the undertaking that no ADRs were reported in Phase I trials conducted in France along with detailed SOPs/ Protocol Validation for samples transportation.*
- *Dr Haleema Shakur -Still will submit the detailed report on the Phase I trials as early as possible.*
- *Fulfilment of all shortcomings under the Bio-Study Rules mentioned in agenda.*
- *The committee finally approved the study.*

(Muhammad Arif Ch.)

Additional Director Pharmacy Services
Secretary Clinical Studies Committee.

Copy to:

- The Chairman, CSC, DRAP, Islamabad.
- F. No.03-48/2020 (DD/PS).

Additional Director Pharmacy Services/
Secretary Clinical Studies Committee.

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