

# Studies on Hormonal Products

## Challenges

### 1. Recruitment of subjects

- Healthy Female subjects
- Postmenopausal Females

### 2. Studies requiring high number of volunteers

### 3. Dose administration and ensuring availability of subjects for ambulatory samples

E.g.: For studies on Vaginal Ring

- Vaginal Ring insertion and removal
- Insertion of Vaginal Ring within specific days of menstrual cycle
- Ambulatory samples collection post Ring insertion

### 4. Subject Retention (Having minimum possible drop outs)

### 5. Requirement of Exquisite Planning

- Study specific screening (requirement of specific Gynecological Tests)
- Handling multiple groups

### 6. Method Development and Validation

- Endogenous hormones (requiring baseline correction)
- Achieving required sensitivity (required LLOQ)

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## Raptim Edge

### ➤ Hands on experience in

Ethinylestradiol + Etonogestrel Vaginal Ring - 0.015mg 24hr and 0.12mg 24hr

Progesterone - 300mg and 400mg Sustained Release tablets

Estradiol and Progesterone - 1 mg/100mg capsules

Ethinyl Estradiol - 0.01mg (2 x 0.01mg dose) tablets

Drospirenone + Ethinylestradiol - 3mg/0.03mg tablets

Levonorgestrel and Ethinyl Estradiol - 0.15mg / 0.03mg tablets USP

Norethindrone Acetate + Ethinyl Estradiol + Ferrous Fumarate - 1mg / 0.02mg /

75mg capsules

- Experienced and well trained team
- Ready database of 4500+ Healthy and Post Menopausal Female volunteers
- Well planned study specific screening
- Well established contact for collaborating with Gynecologists for Vaginal insert/ring, etc.
- Practice of adherence to study protocol and counseling the subjects to have the required retention of volunteers
- Validated methods available for all the molecules mentioned under Raptim Experience