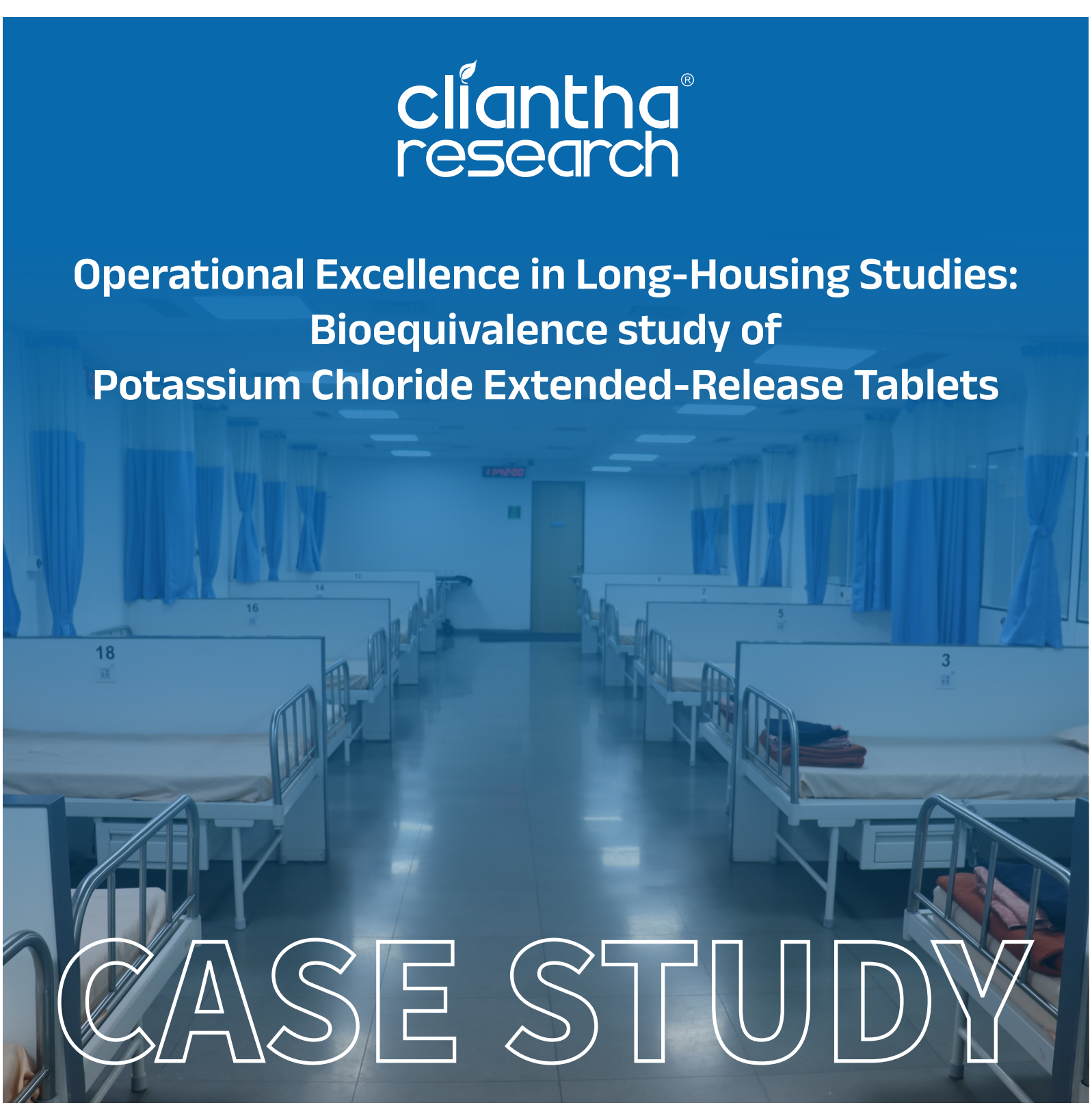
cliantha® research

Operational Excellence in Long-Housing Studies: Bioequivalence study of Potassium Chloride Extended-Release Tablets



CASE STUDY

Challenges

1) Inclusion criteria: Narrow age group (20-40 years)
2) Long Housing Confinement – Continuous housing from Day 1 to Day 16
3) Administration of 8 tablets in one go
4) Dietary Restrictions: Standardized meal from Day 1 to 16 with calculated daily intake of Potassium, sodium, and calories.
5) Monitoring of fluid input/output
   - Accurately measured quantity of water to be given at multiple times
   - Subject compliance challenges
6) Sample collection
   - Missed collections, common at night and during rest periods
   - Adherence to time points
7) Post first dosing, creatinine clearance levels and fecal blood determination were to be evaluated to determine subject's eligibility for continuation of trial.

Mitigation Strategies Framework

1) Strategic In-House Recruitment Execution
   - Dedicated recruitment team operating from within the facility for faster screening and enrollment
   - Use of Cliantha's proprietary volunteer database to identify eligible subjects (age 20–40) quickly
2) Narrowed the funnel by informing subjects regarding:
   - Study duration
   - Fully compliant subjects were considered, avoiding dropouts and ensuring timely achievement of required sample size
   - Rationale behind the food/calorie restrictions
3) Real-time lab results from our on-site clinical facility for fecal blood determination and creatinine clearance estimation levels led to faster decisions, and safer volunteer selection
4) To support pharmacokinetic accuracy and subject safety, water intake was managed diligently by a trained in-house team
5) Our core strength - Having an in-house clinical nutrition expert to formulate precise, study-aligned diets to manage electrolyte balance and meet regulatory expectations.

Conclusion:

Managing long-housing clinical studies such as Potassium Chloride Extended-Release Tablets , demands a CRO partner with specialized expertise and proven experience to navigate the challenges inherent in such trials.

With over 20 years of experience in clinical research, Cliantha's strength lies in its robust operational capabilities, making it ideally equipped to manage complex, long-duration in-house studies with precision and regulatory compliance. By integrating an in-house clinical laboratory, trained staff, and real-time volunteer management systems, Cliantha ensures protocol adherence, subject safety, and data integrity.

This study highlights Cliantha's proven ability to execute high-complexity trials involving extended confinement, stringent dietary controls, and time-sensitive evaluations—seamlessly conducted under one roof with efficiency and accuracy.

For more information,
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Meet us at

CPHI Frankfurt

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Booth: 3.1A36