

Summary of the Validation Report for the Covance Human Appetite Laboratory, Leeds

The Human Appetite Laboratory (HAL) at the Covance Clinical Research Unit in Leeds is designed for the conduct of test meal assessments in Clinical Pharmacology studies. These data provide valuable information on the ability of potential anti-obesity compounds to suppress appetite and enable Proof-of-Concept data in the target population to be obtained as early as the First-in-Human study.

The HAL facility comprises four isolation booths and a food preparation area, with strictly controlled test meals being prepared by on-site chefs. Prior to use of the HAL facility on a clinical trial, all staff involved in test meal assessments (i.e. both chefs and operational staff) were fully trained and a validation study was performed to determine the precision and sensitivity of the test meals assessments.

The precision validation test consisted of a panel of six healthy subjects, each eating a test meal on three separate occasions. The sensitivity validation test consisted of a panel of eight healthy volunteers, each eating a test meal with and without prior consumption of a high protein drink (administered in accordance with a randomisation schedule).

Precision of test meal assessments

When performing test meals assessments on six subjects across three test meal days, the precision of energy intake varied between 91.5 to 104.8% of the overall mean value. This equates to a maximum variation in energy (kcal) intake of 13.3%, which complies with the pre-defined acceptance criteria of $\leq 20\%$.

The total weight of food consumed ranged from 97.2 to 103.4% of the overall mean giving a variation of 6.2% across three days.

Sensitivity of test meal assessments

Administration of the pre-test meal drink to eight subjects reduced mean energy intake (kcal) by 24.4%, which complies with the pre-defined acceptance criteria of $\geq 10\%$.

Conclusion

Test meal assessments performed using the Covance Human Appetite Laboratory at Leeds are of good precision and high sensitivity, thereby ensuring the provision of robust food intake data.