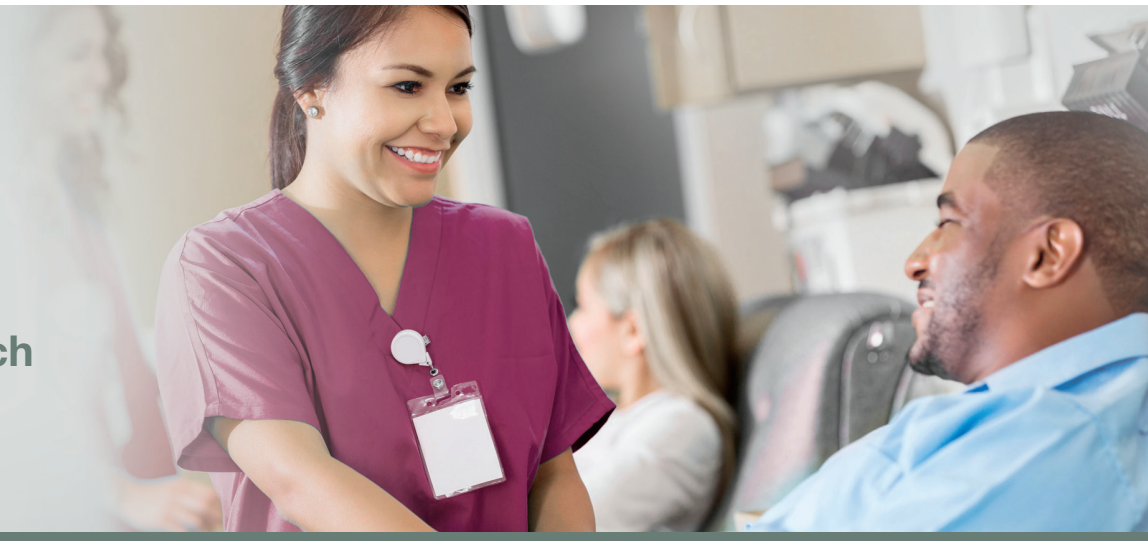
Customer Focus

Clinical Expertise

Innovative Approach



Semen Clinical Studies

NEED

- The client required study to be conducted to remove regulatory hold
- When animal model studies suggest that there may be adverse testicular effects due to a study drug, spermatogenesis needs to be evaluated to see if the effects are reflected in humans
- Many drugs distribute into seminal fluid and may have direct effects on sperm function, physiology or sperm motility. Clinical studies can examine the semen exposure to the study drug and the potential effects on semen parameters

APPROACH

- Conducted reproductive safety evaluations including: sperm concentration, motility, morphology, viability, and others on over 1200 samples
- Provided triplicate baseline semen analysis on 165 participants in < 1 month
- Enrolled large panels and performed semen analysis on 50+ participants in a day
- Celerion bar code system tracked semen samples retention for PK analysis
- Semen analysis captured in our ClinQuick® integrated laboratory results system for easy Principal Investigator review and data extraction
- Rapid recruitment of 300 participants in 2 days for long term semen studies
- Multi-site approach to facilitate ethnicity stratification as per client's request
- External Advisory Board facilitated semen analysis data review, including experts in toxicology, reproductive medicine, and a statistician

BENEFITS

- Celerion's specialized semen study capability allowed us to deliver services that enabled the client to transition to the next stage in the product development and deliver key safety information to the regulatory agency
- To assist the client in making informed go/no-go decisions on their compound in development as early and quickly as possible

See Other Case Studies

Bioanalytical Support of Oncology Studies

Standardizing Database Structure for Programs

IND Support for Asian Biotech