CASE STUDY
STUDYING SEDATIVES IN PHASE I STUDIES

A biotech Sponsor approached QPS to conduct a challenging Phase I study, involving a bolus injection of a rapid onset sedative/anesthetic in healthy volunteers. This case study outlines the challenges we faced and the solutions we put in place to deliver the study successfully.

CHALLENGE

The Sponsor contracted QPS to deliver an extremely complex study that required Operating Room-like facilities, intense safety measures, and close collaboration with local hospital experts.

SOLUTION – 3 FACTORS FOR SUCCESS

Safety-First Approach:

- Intense safety assessments we put in place, including ECGs (12-lead and 3-lead) and respiratory function (respiratory pattern and occurrence of apnea)
- Anaesthesiologist and an anaesthesiology nurse present and working closely with the QPS dedicated team at all times during dosing

World Class Facilities:

- QPS established a dedicated Operation Room-like (OR-like) facility
- RUGLOOP electronic data capture system used for the duration of the trial

Phase I Expertise:

- Collaboration between QPS and the Dept. of Anaethesiology of the UMCG
- PD measures: time to onset, level, emergence from and duration of sedation/anesthesia, MOAA/S scale and Bispectral Index Scores (BIS)

OUTCOME

QPS exceeded the Sponsor's expectations, delivering an extremely complex, early phase clinical trial, by working closely with local hospital-based experts and providing a dedicated facility and team.