A Phase II anti-infective study involving a new biotech drug against pneumonia

Situation: The study consisted of a Phase II trial for pneumonia comprising of a unique IP

Challenges:

- Due to the unique nature of the IP, convincing investigators about its therapeutic potential was a challenge
- Site identification was of crucial importance, since some sites lacked the necessary infrastructure for serotyping, as required by the study protocol

SIRO Strategy:

- SIRO worked closely with the sponsor to prepare in advance the study manual, manuals for all molecular/microbiological techniques, a time schedule per day of study, CRF completion guidelines, laboratory guidelines
- SIRO identified the sites based on its recruitment potential & for the quality of data generated
- SIRO identified an external lab for conducting rapid serotyping

Result:

- SIRO sites in Greece were able to enroll 23% of all study patients
- The data generated from the enrolled patients generated was of high quality
- Based on the quality of the data & an audit conducted by the client, the sponsor chose the SIRO sites as the 'central sites' for the IP's next stage trial