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## 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.

