Accelerated subject recruitment in an injectable nanovalent HPV Vaccine Study

Situation: Phase III randomized multi-national study of an injectable nanovalent HPV vaccine. 225 subjects to be recruited at 7 sites in 120 days in India, boys & girls between age groups 9 and 15 years & only females between age groups 16 and 26 years. The vaccine was to be administered in the 1st month, 3rd month & 6th month of study.

Challenges:

- Difficult to recruit and enroll pediatric subjects
- Subject retention due to mode and frequency of drug administration
- Approvals from two different authorities within our regulatory framework due to nature of IP
- By the time approvals were received from local authorities, the enrolment time was reduced from 120 days as per protocol to only 15 days
- Maintenance of cold chain due to nature of IP and the inter site geographical distances

SIRO Strategy:

- SIRO screened sites in anticipation of challenges from local health authorities due to nature of the IP
- SIRO experts ensured training of naïve sites to bring them up to the standards required by the sponsor
- A strategy of co-monitoring was developed wherein the clinical monitor visited the site on the very next day of patient screening
- SIRO team prepared a comprehensive plan to ensure rigorous follow up in coordination with the investigators to ensure subject adherence to study protocol and maximize subject retention

Result:

- First patient randomization done next day of obtaining clearance from Central Drug Laboratory. 2 patient randomizations were done on the very first day.
- Last patient randomization was achieved 3 days prior to global 'last patient in' deadline
- 225 subjects were recruited in only 15 days

Sponsor Feedback:

"Congratulations for achieving FSI in the study. The credit goes to everyone. I must admit that everybody has put in their efforts passionately. Please don't let the passion die...continue to do your best!"

- Sponsor Clinical Operations Head