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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 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.





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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.

