Biotechnology Innovation Organization

Industry Perspective: Considerations for COVID-19 Vaccine Pediatric Trials

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Need for COVID-19 Vaccines for Pediatric Populations

- *Sponsors support FDA in their recognition of the need for COVID-19 vaccines for pediatric populations.*
  - Children generally have had lesser disease burden from COVID-19 infection than adults throughout the pandemic; however, children can have severe and long-lasting outcomes from COVID-19 infection.
  - Vaccination is increasing but strategies focused on immunization of adults only will undermine efforts to achieve herd immunity if there is ongoing circulation in children perpetuating the pandemic.

Pediatric Vaccine Clinical Trials

- *Sponsors have decades of experience collaborating with FDA on pediatric vaccine clinical trials.*
- *FDA is upholding the same high standards for COVID-19 vaccine trials.*
  - **Randomized control trials (RCTs):** FDA is requiring robust data from the "gold standard" in clinical trials.
  - **Age de-escalation, immunobridging, and dose ranging:** A step-wise approach to age-based studies is a normal process in rigorous clinical trials.
  - **Safety monitoring:** Vaccine safety databases in use in the US collect important information on the safety of vaccines in all populations, including pediatrics.

Questions for FDA

- Can FDA comment on the regulatory pathway for authorization of a lower pediatric dose(s) compared to the dose authorized in adults? Would immunobridging support use of a lower dose in pediatrics?
- What are the FDA's plans for vaccine effectiveness studies in pediatric populations? What are expectations for sponsors with regard to vaccine effectiveness studies? How will FDA and sponsors collaborate on vaccine effectiveness studies?
- How should sponsors approach coadministration studies and concomitant use of COVID-19 vaccines and other vaccines for pediatric populations?
- How will FDA use data from pediatric populations from safety monitoring systems used for COVID-19 (i.e., V-Safe)?
- How does FDA intend to collaborate with other regulators to ensure global alignment for COVID-19 vaccine pediatric programs?
- How will FDA's approach evolve as COVID-19 moves from the pandemic period to a more endemic stage?