



Protocol Considerations for Infant Vaccines

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Protocol Considerations for Infant Vaccines

- ▶ Must show safety in adults first
 - ▶ Followed by studies in adolescents, toddlers, then infants
 - ▶ Combination with other pediatric vaccines
 - ▶ Placebo arms are frowned upon. Advise active control.
 - ▶ Buy-in from pediatricians
 - ▶ Recommendations from pertinent Advisory Committees
 - ▶ Safety studies typically involve 5,000-10,000 infants.,
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