

Overview on Vaccine Clinical Development

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What is clinical research and development of vaccines?

- It is the science and operations of experimenting vaccines in humans
- **Clinical research and development** of vaccines include several phases from I to III (prior licensure) to IV (post-licensure)
- **Clinical research** is often used for early clinical development such as phase I trials or human challenge trials
- For the purpose of this training clinical development will be used

Vaccine Clinical Development

- **Clinical data** are an essential part to obtain vaccine licensure and vaccine acceptance
- **Vac Clin Dev** is a highly specialized discipline which requires complex conceptual, planning and operational competences
- **Vac Clin Dev** is highly regulated discipline by ethical, scientific and regulatory guidelines



DoH, ICH-GCP, WHO, EMEA, USA FDA, National Guidelines

