



## *Little Door to the Thirteenth of December*

### Vaccination Facts: The different Phases!

Without the advances humanity made in medicine, vaccines in particular, a lot of us would probably have died in our childhood or might have been impaired for life (e.g. polio). So, for this little door we take a closer look at the phases a vaccine has to go through.

Phase	Summary
Pre-Clinical	<b>Before Human Trials</b>
	<ul style="list-style-type: none"> <li>Robust data from laboratory required</li> <li>Investigators and an independent ethic committee must be confident that is both very likely to be safe and effective</li> </ul>
Phase 1	<b>Volunteers: ~ 100</b>
	<b>Primary Objective: Safety</b> <ul style="list-style-type: none"> <li>It is expected to be safe from the animal testing</li> <li>Blood tests are collected from the volunteers to test the efficacy of the vaccine (did an immune response occur?)</li> <li>Multiple doses used to find the ideal dose for later trials</li> <li>Subjects are healthy with no comorbidities to ensure safety and avoid confounders</li> </ul>
Phase 2	<b>Volunteers: 1,000 to 2,000</b>
	<b>Primary Objective: Safety</b> (studies of effectiveness also conducted) <ul style="list-style-type: none"> <li>The volunteers begin to be more diverse (e.g. broad age range) to better resemble the population</li> <li>While it gives first insights into the actual protection from a pathogen, these studies are not large enough to confirm that it provides protection</li> </ul>
Phase 3	<b>Volunteers: 10,000 +</b>
	<b>Primary Objective: Efficacy</b> (safety still remains a focus) <ul style="list-style-type: none"> <li>Shows whether the vaccine significantly lowers infectiousness</li> <li>Size of volunteers depends on how wide-spread the disease is</li> <li>In any phase a vaccine can fail to show that it provides sufficient protection; a number of vaccines candidates fail in phase 3 studies</li> </ul>
Phase 4	<b>Vaccine has been approved</b>
	<ul style="list-style-type: none"> <li>The approved vaccine is being widely used</li> <li>Data is still being collected on its safety and how well it works</li> </ul>
Source: Medical Express (2020-08)	
Link: <a href="https://medicalxpress.com/news/2020-08-vaccine-clinical-trial-phases.html">https://medicalxpress.com/news/2020-08-vaccine-clinical-trial-phases.html</a>	