PHASES OF CF CLINICAL RESEARCH

Phase

Length

Number of People*

Purpose

Phase 1



1 month



10-20



Is it safe?



How does the body process it?



What are the side effects?

Phase 2



3 - 12 months



50-75



Is it safe?



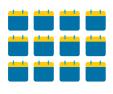
How well is it working?



How much should be taken?

Phase 3

If successful



6 - 12 months



100-300



Is it safe?



How well is it working?



Does the benefit outweigh the risk?

FDA Approva



Application submitted



Application reviewed







→

Available

Application Available approved to public

(6-12 months)





3 - 12 months



100-300



Does it still appear to be safe?



Are there rare side effects?



Cost effectiveness & comparison to other similar drugs



= 15 healthy participants



= 15 participants with CF



 Number of months of participant involvement

