Is it the right choice for you?

Recently, we wrote about a recent clinical trial for the drug ASP2151. Developed by Astellas Pharmaceuticals, ASP2151 may increase the time between outbreaks and may provide an alternative treatment for those who have developed HSV drug resistance or are non-responsive to current medications. Recently, we learned all participants in phase II of the trial have completed the study and researchers will conduct a data review in October. Hopefully, we will have more to share in the future.

However, did you know ASP2151 already appears promising by almost completing the second phase of the clinical trial process? According to CenterWatch, a clinical trial listing service, only a third of experimental drugs finish phase I and phase II successfully. If you have ever wondered why the participants in this trial or any trial choose to participate or just wondered what happens during a trial, this article is for you.

Clinical trials test a drug's safety and efficacy in humans. Phase I of a trial is done to assess a drug's safety. Participants in this phase are usually healthy volunteers. This stage enables researchers to develop a safe dosage for the drug or treatment and identify side effects.

Phase II of a trial helps to further identify side effects and evaluate effectiveness, depending on the condition. For some interventions only phase III studies are able to assess effectiveness. Participants in this phase usually have the disease or condition the experimental drug or tr

eatment would address.

Phase III could be characterized as the expansion of phase II. In this phase a larger number of participants are used and the drug is further evaluated for effectiveness. During this phase the drug is compared to currently available treatments. If no treatment is currently available for the disease or condition, the experimental drug is compared to a placebo—an inactive substance that has no medication. Those who are randomly chosen to get the placebo are unaware that they are in fact taking it and not the actual drug, although all participants are told that they may

get the drug or the placebo. If the drug is not safe, you would be fortunate to be in the placebo group.

If the drug is successful in phase III and receives clearance from the Food and Drug Administration (FDA), further study may be done once it is on the market to gather more information regarding the drug's benefits and risks. This is considered Phase IV.

So why participate in a clinical trial? For one, testing in animals can only tell you so much about how the drug may work in humans. By participating in a clinical trial you provide researchers with vital information that will eventually help many people. Additionally, being paid for participation doesn't hurt either. For those who considering trial participation, www.clinicaltrials.gov, a registry of federally and privately supported clinical trials from the National Institutes of Health, lists the following benefits and risks of trial participation:

Benefits for participants:

- Play an active role in their own health care.
- Gain access to new research treatments before they are widely available.
- Obtain expert medical care at leading healthcare facilities during the trial.

Risks for participants:

- There may be unpleasant, serious or even life-threatening side effects to experimental treatment.
- The experimental treatment may not be effective for the participant.
- The protocol may require more of their time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.

What if the drug or treatment fails during the trial and never makes it to market, would my time be wasted? No. Throughout the clinical trial data is gathered and reviewed. Even if the drug never makes it to market the data gathered may prove invaluable for future studies or for re-evaluation of the failed drug or treatment. It is better to have the drug fail during trials than to make it to market and have unsuspected adverse events occur in patients receiving the treatment or drug. Whether the treatment makes it to market or not your participation provides researchers with vital information that may benefit many.

Considering trial participation? You may want to speak with others who participated in trials

previously and learn what their first hand experiences entailed. Additionally, you may want to visit clinicaltrials.gov and centerwatch.com for further information on clinical trials before making your final decision.