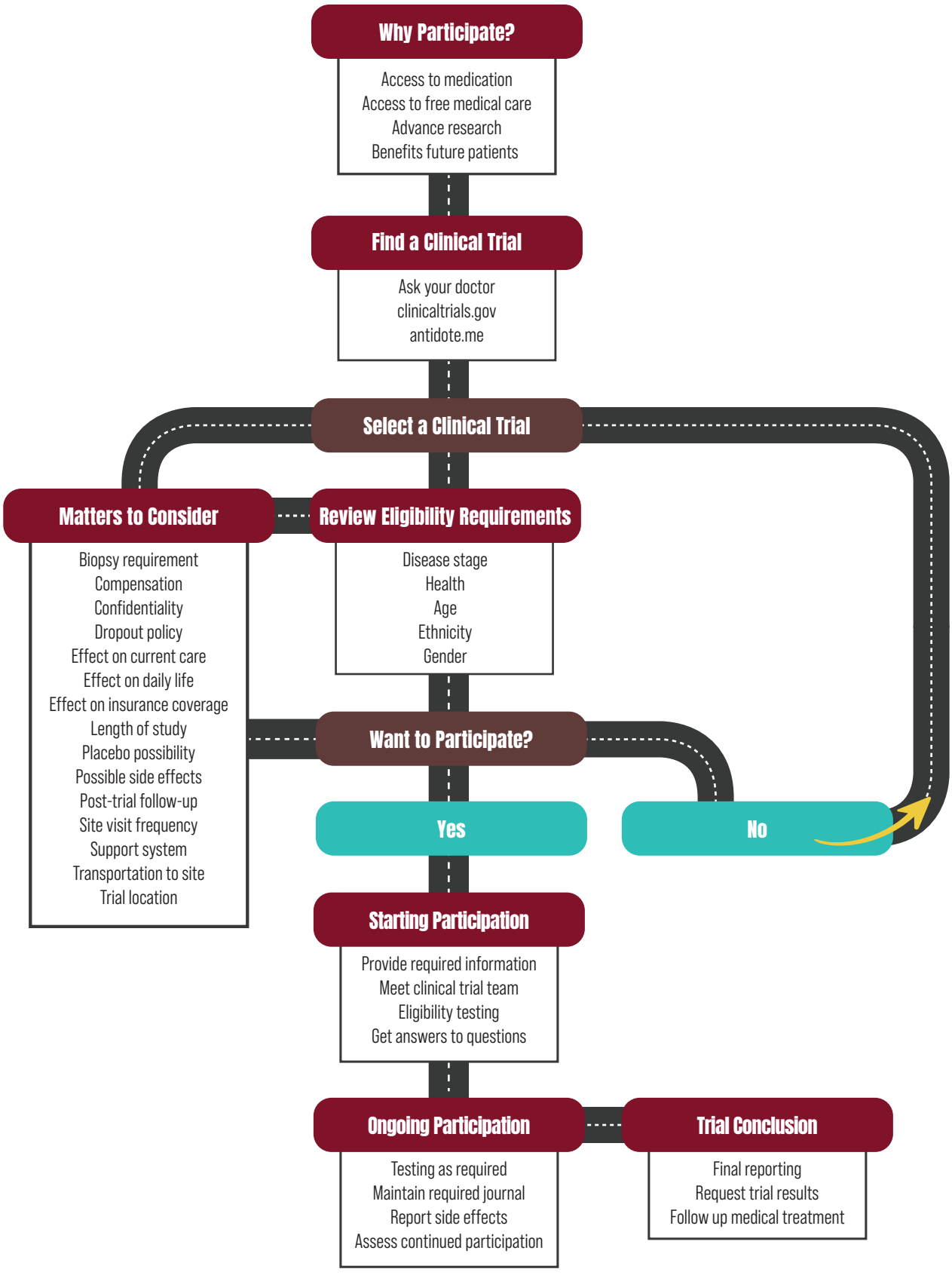
CLINICAL TRIAL ROAD MAP



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WHY A CLINICAL TRIAL?

A drug cannot be marketed in the United States without prior FDA approval. Clinical trials are conducted to get FDA approval. This is usually a lengthy and expensive process that requires the completion of three phases before approval and a fourth phase post-approval. Each phase is described by the U.S. Department of Health and Human Services as follows:

PHASE 1

A Phase I trial tests experimental treatment on a small group of often healthy people (20 to 80) to judge its safety and side effects and to find the correct drug dosage.

PHASE 2

A Phase II trial uses more people (100 to 300). While the emphasis in Phase I is on safety, the emphasis in Phase II is on effectiveness. This phase aims to obtain preliminary data on whether the drug works in people with a certain disease or condition. These trials also continue to study safety, including short-term side effects. This phase can last several years.

PHASE 3

A Phase III trial gathers more information about safety and effectiveness, studying different populations and dosages and using the drug in combination with other medications. The number of subjects usually ranges from several hundred to about 3,000 people. If the FDA agrees that the trial results are positive, it will approve the experimental drug or device.

PHASE 4

A Phase IV trial is conducted after a drug is approved by the FDA and made available to the public. Researchers track its safety in the general public, seeking more information about a drug or treatment's benefits, and optimal use.

PLACEBO GROUP

Participants in the study are divided between those who receive the treatment and those who receive a placebo or a well-established treatment. Patients are randomly assigned to each group and typically do not know which group they are in.

Even those in the placebo group gain from participation as they have access to excellent medical care and also have the satisfaction of helping to advance new treatments that will benefit future patients.

The US Department of Health and Human Services has published a list of questions to consider when considering trial participation. Here is the link: https://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/questions-to-ask/index.html

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