

# The Importance of Clinical Trials & The Role of Diversity

Clinical trials are research studies involving human volunteers that investigate how an experimental treatment or intervention might prevent, detect or treat a disease.<sup>1,2</sup>

They are key to medical advancements and the drug development process, as they provide the insights and answers researchers need to bring innovative treatments and interventions to patients.

Clinical trials are often conducted to evaluate potential treatments for patients where currently available options don't fully address unmet need. They are in many ways the last few steps in a potential therapy or intervention's development, with years of work culminating in a well-designed effort to understand efficacy and safety in patients so that a new option may be offered to those in need.

To truly understand the efficacy and safety of an experimental treatment, individuals within the clinical trial should be representative of the population who might one day be prescribed the treatment. Recognition of the need of a more diverse representation has prompted an industry-wide effort on inclusive medical research.

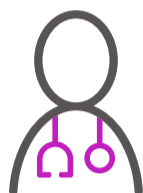


## What Can Clinical Trials Study?

Clinical trials can study a variety of treatments and interventions<sup>1</sup>



Drugs or drug combinations



Methods for surgery



Medical devices



New ways of using existing treatments



Behavior changes



Ways to improve quality of life in acute or chronic illness

## Planning for a Clinical Trial

A clinical trial is an experiment, and must be designed so that the hypothesis being tested can be proved or disproved at the end of the study. All aspects of the trial must be carefully planned for and detailed in the study protocol, including<sup>2,3</sup>:

- Why the study is being done
- Who can participate
- The required number of participants
- The groups the participants will be broken into
- What is going to be measured and monitored
- How long the trial will take place
- Where the trial will take place
- What can participants expect



## Conducting a Clinical Trial

Once designed, clinical trials are ready to begin. But this cannot happen without volunteers.

Ability and willingness to participate in a clinical trial often depends on how easy it is for a patient to get to a trial site.

A key challenge is designing trials in such a way that patients have easy access to trial sites, regardless of their geographical location. Ensuring access to clinical trials is a key driver of clinical trial diversity.

- Including diverse populations ensures that the trial participants are truly representative of the patients who suffer from the condition under study.
- The gender, age, race, ethnic origin and other patient characteristics can sometimes play a role in how a potential treatment may work in a patient.



Recruited patients are then screened for eligibility to participate in the trial. If qualified and willing to participate, patients then become participants.

Participation typically involves:

- Full understanding of the investigative study, or Informed Consent
- Completion of study visits
- Treatment with the investigational medicine or placebo (inactive drug for comparison)
- Testing
- Monitoring

*Participation is voluntary and participants are free to withdraw from the study at any point in time.*

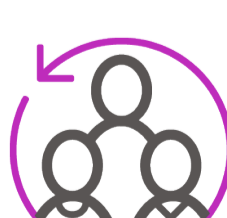


## A Commitment to Increasing Diversity

Bristol Myers Squibb is committed to improving the design and operation of clinical trials by accelerating and expanding health equity and diversity and inclusion efforts.



Bristol Myers Squibb and the Bristol Myers Squibb Foundation are each committing **\$150 million** to accelerate and expand health equity and diversity and inclusion efforts, including efforts to increase clinical trial diversity.



Over the next five years, Bristol Myers Squibb will further extend the reach of trials into underserved patient communities and the Bristol Myers Squibb Foundation will train and develop **250** new racially and ethnically diverse clinical investigators that can enroll a diverse patient population in trials conducted across the industry.

1. <https://www.nih.gov/health-information/nih-clinical-research-trials-you-basics>  
 2. Learn About Clinical Studies - ClinicalTrials.gov. Accessed July 7, 2021. <https://clinicaltrials.gov/ct2/about-studies/learn>  
 3. Bossel J-P. Planning of clinical trials. J Intern Med. 2004;255(4):427-438. doi:10.1111/j.1365-2796.2004.01311.x