

# Understanding Cardiovascular Clinical Trials

## The Shifting Cardiovascular Landscape



Cardiovascular disease is the most common cause of mortality and represents nearly **1/3 of deaths globally**, demanding new approaches for disease prevention and control.<sup>1</sup>

As cardiovascular medicines have become more effective and new regulatory and safety mandates have been enacted, **increased clinical evidence is needed** to support new advances, requiring increased size, scope and complexity of cardiovascular clinical trials.<sup>2</sup>

## Clinical Trials in Cardiovascular Disease



Most cardiovascular diseases are chronic and require **long-term treatment**. Trials that demonstrate clinical risk reduction are typically longer in duration, will require a higher number of patients, and may require more complexity to account for the changing treatment landscape and to appropriately assess safety.<sup>2-3</sup>



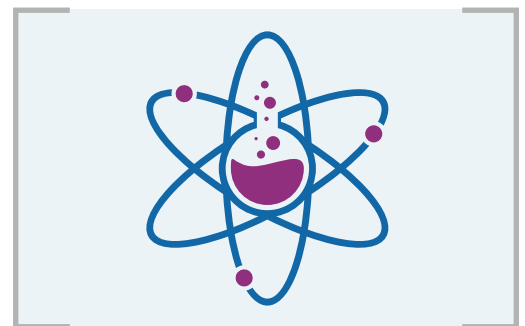
Prevention trials involve **healthy people at high risk** for developing cardiovascular disease or who have had cardiovascular disease and are at high risk for experiencing a new vascular event. This is in contrast to clinical trials studying potential new treatments where all participants are diagnosed with the condition.



In a cardiovascular prevention trial, a **high number of patients are enrolled** as most will not experience an event. These trials often include a **background therapy**, so trials must demonstrate additional effect.

## A Need for New Innovation

Due in part to the large investment required to run these complex trials, the number of cardiovascular drugs researched has **declined across all phases of development** in the last 20 years. In the last five years, cardiovascular agents comprised just **6% of all new drug launches**.<sup>4</sup> However, cardiovascular disease remains the number one cause of death globally and this patient population faces significant unmet needs.



**Rooted in a long-term commitment to patients with cardiovascular disease, Bristol-Myers Squibb is contributing to cardiovascular research by investing in clinical trials with the goal of delivering transformational patient outcomes.**

1. Cardiovascular diseases (CVDs), World Health Organization. Accessed February 23, 2018. <http://www.who.int/mediacentre/factsheets/fs317/en/>  
2. S. Solomon, et al. The Future of Clinical Trials in Cardiovascular Medicine. *Circulation*. 2016;133:2662-2670  
3. N. Jackson, et al. Improving clinical trials for cardiovascular diseases: a position paper from the Cardiovascular Round Table of the European Society of Cardiology. *European Heart Journal*. 2016;37:747-754.  
4. G. Van Norman. Overcoming the Declining Trends in Innovation and Investment in Cardiovascular Therapeutics. *JACC: Back to Translational Science*. 2017;2:613-625.



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