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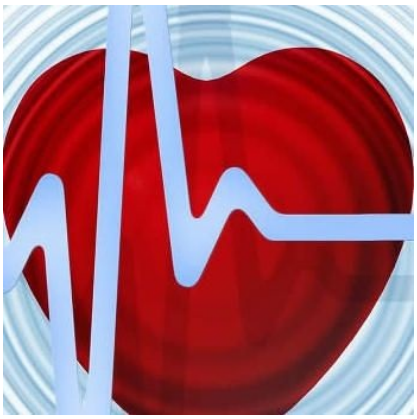
Simplified Clinical Trials to Sustain Innovation



According to the Cardiovascular Round Table (CRT), randomised controlled trials must be simplified to sustain innovation in cardiovascular diseases. CRT is an independent forum established by the European Society of Cardiology (ESC). The views of the group are published in the *European Heart Journal*.

Professor Paulus Kirchhof, corresponding author, highlights the fact that cardiovascular disease continues to be the biggest killer in Europe and is responsible for significant morbidity and burden to the health care system. Despite this, drug developers do not feel inclined to develop new cardiovascular medicines because of high perceived risk and development cost.

A major barrier to cardiovascular research is the investment that is required to conduct clinical research. It costs approximately $12 billion to bring a single drug to the market. In addition, regulatory reviews often take a long time leaving a very short window for developers to recoup their costs before the patent expires. Thus, such an investment is considered high-risk and the funding of outcome trials in cardiovascular medicine is avoided.

The authors point out that randomised controlled trials have become bloated and inefficient and may be a major barrier for drug development. There are certain aspects of cardiovascular medicine that make investment in the development of cardiovascular drugs less attractive as compared to other fields of medicine. These include:

- Long-term treatment of most cardiovascular therapies.
- Difficulty in demonstrating incremental risk reduction
- Difficulty in identifying patients who are likely to benefit
- Complex clinical trials that often contradict national and regional regulations

Prof Kirchhof said: “Cardiovascular drug development is partially a victim of its own success, where mortality benefits are the accepted benchmark in the field, and new therapies have traditionally been evaluated in large cohorts. We have developed ever more robust systems to conduct such trials, and are now faced with a total cost that seems prohibitive for some of the novel developments. Progress in prevention of cardiovascular diseases may require more stratified or personalised management approaches in the future.”

Other obstacles to cardiovascular drug development include the high cost when drugs fail in late stage clinical trials. The authors recommend certain solutions to reinvigorate investment in cardiovascular research including targeted drug development and evaluation in defined patient populations, as well as the simplification of large randomised trials. The authors suggest a streamlined pre-approval evaluation process and for agents to be initially tested and approved for a smaller target population. Additional safety and efficacy data can then be collected once the initial approval is obtained. This could mitigate the risk for drug developers and can also

enable them to provide patients quicker access to the drug.

Prof Kirchhof also recommends that the resource use in controlled trials should be reduced and IT based health and social records should be used to collect information on death and cardiovascular outcomes. He emphasised on the need to find novel approaches to develop new therapies and the important role regulators can play in ensuring that only safe therapies are approved.

Source: European Society of Cardiology (ESC)

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