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## Neuralink Set to Begin Human Trials



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Elon Musk's controversial biotechnology startup, Neuralink, announced that they have received approval from the independent institutional review board to commence recruitment for its first-in-human clinical trial. The **P**recise **R**obotically **I**mplanted Brain-Computer Interface (BCI) (PRIME study) will investigate brain implants in individuals suffering from paralysis. The primary goal of the study is to assess the safety of the N1 Implant and R1 Surgical Robot and evaluate the functionality of the BCI. It is believed that the implant could enable individuals with paralysis to control external devices using their thoughts.

The R1 Robot will perform the surgical placement of the ultra-fine and flexible threads of the N1 Implant in a specific region of the brain responsible for controlling movement intention. Once in situ, the N1 implant will become cosmetically invisible. The implant will also wirelessly record and transmit brain signals to an app, which will decipher these signals and translate them into movement intentions. The goal is to use the BCI to empower individuals to control a computer cursor or keyboard through their thoughts.

The PRIME Study operates under the investigational device exemption (IDE) granted by the FDA in May 2023, marking a significant stride in Neuralink's quest to develop a universal brain interface that can restore autonomy to those with unmet medical needs.

Individuals afflicted with quadriplegia due to cervical spinal cord injury or amyotrophic lateral sclerosis (ALS) may meet the criteria for participation in this study. It will be a six-year study with 18 months of at-home and clinic visits and then five years of follow-up appointments.

Elon Musk's company has been working on connecting the human brain to a computer via implants for the past five years. But so far, the company has limited its testing to animals. There was significant controversy in 2022 when a monkey died during a project to teach the animal to play Pong, a video game.

The FDA had initially rejected the application for human trials, citing concerns about the implant migrating within the brain and potential brain tissue damage during removal. However, the company submitted more paperwork and has now received clearance.

Neuralink will still need regulatory approval before its brain implants become available to a wider audience.

Source: [Neuralink](#)

Image Credit: iStock

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