

## Advancing Research Through Clinical Trials: Insights from Dr. Akbar Niazi Teaching Hospital, Islamabad

Ahmad Farooq<sup>1,2</sup>, \*Areej Neyazi<sup>1</sup>, Usman Waheed<sup>2</sup>

<sup>1</sup>Clinical Trials Unit, Dr. Akbar Niazi Teaching Hospital, Islamabad, Pakistan

<sup>2</sup>Department of Allied Health Sciences, Islamabad Medical and Dental College, Islamabad, Pakistan

Clinical research plays a crucial role within healthcare institutions and academic settings, encircling a broad spectrum of medical investigations aimed at evaluating the efficacy of drugs, surgical procedures, and medical devices used in patient treatment and management.<sup>1</sup> It involves rigorous studies conducted to assess the safety and effectiveness of clinical practices, thereby advancing healthcare services. Engaging in research within healthcare organizations offers extensive benefits, including reduced staff turnover, increased productivity and efficiency, and lower patient mortality rates.<sup>2</sup>

Clinical trials, a pivotal component of this process, are systematic studies involving human subjects. They assess various aspects of drugs or devices, including their efficacy in treating specific diseases or conditions, their role in diagnosis and screening, their impact on patient management, and their overall potential in disease prevention and treatment anticipation. Advancements in clinical practice usually require level one evidence from clinical trials that directly compare new approaches to standard of care.<sup>3</sup>

Clinical trials are usually categorized based on their purpose. By that standard, there are five different types of clinical trials as follows; (1) Treatment trials,

which assess new drugs, therapies, devices, or surgeries; (2) Prevention trials, which evaluate methods to prevent diseases through medicines, vaccines, or lifestyle changes; (3) Diagnostic trials, which test new ways of diagnosing diseases or conditions; (4) Screening trials, which examine new methods of detecting diseases or conditions early; and (5) Quality of life trials, which explore new methods to enhance the quality of life for individuals with chronic disorders.<sup>4</sup>

The most common type of clinical trial is termed parallel-arm experiment, in which study participants are divided into at least two groups. Preferably, the members of both groups are the same in every way except one: some obtain the treatment under test (active group); while others do not receive the treatment (control group).

The journey of clinical research, from ancient trials to modern standards, marks a saga of scientific, ethical, and regulatory evolution. The first recorded experiment resembling a clinical trial was conducted by King Nebuchadnezzar during 605 BC to 562 BC.<sup>5</sup> Thereafter, the first ever clinical trial for novel therapy was accidentally carried out in 1537 by Ambroise Parè, who was responsible for the treatment of the battlefield wounded soldiers. Due to the short supply of recommended treatment for wounded patients, he used some homemade oil and recorded his findings.<sup>6</sup> Later in 1747, a British naval ship doctor, James Lind, performed first parallel arm experiment by testing numerous scurvy treatments

\*Director, Clinical Trials Unit, Dr. Akbar Niazi Teaching Hospital, Islamabad, Pakistan.  
Email: areej.neyazi@danthospital.com  
DOI: <https://doi.org/10.35787/jimdc.v13i2.1257>

on crew members and revealed that lemons and oranges were most effective in treating the disease.<sup>7</sup> In 1863, Dr. Austin Flint a USA based physician, conducted the first experimentation on comparing a dummy remedy with a previously existing remedy.<sup>8</sup> Schwartz and Lellouch were the first to use the word 'pragmatic' in relation to clinical trials in 1967. They defined a pragmatic trial as a trial designed to help choose between care options, as opposed to an explanatory trial which is used to test causal research hypotheses, for example about biological processes.<sup>9</sup>

The year 1947 saw a major shift in the way clinical trials were being conducted, for the Nuremberg Code was established with its 10-point system.<sup>10</sup> The Declaration of Helsinki came next, formulated by the World Medical Association (WMA) to provide a list of ethical codes for medical professionals, researchers, and study participants of clinical trials.<sup>11</sup> However, the second half of 21<sup>st</sup> century set a benchmark for clinical trials when most of the advancements and regulatory frameworks were introduced to conduct clinical trials.<sup>12</sup> The highest standard of quality and ethics required to conduct a clinical trial brought in the concept of establishing Clinical Trial Units (CTUs), that has reformed the scenario of these studies. CTUs are specialized biomedical research units which have been set up with a specific remit to design, conduct, analyze and publish clinical trials and other well-designed studies.<sup>13</sup> International Clinical Trials Registry Platform (ICTRP) data reveal that there are currently over nine million clinical trials registered worldwide till June, 2024, with nearly 38.4 % being conducted in Asia.<sup>14</sup> Pakistan at one hand is the sixth largest populated country but also has significantly higher disease burden contrary to the neighboring south Asian countries. That surfaces a critical need to conduct systematic and dedicated clinical trials to resolve health related issues of the local population.<sup>15</sup>

CTUs have played a key role in the conduct of clinical trials and according to the set standards as

formulated by the international and local authorities ensuring the data integrity, and participant safety of the participants.<sup>16</sup> The CTUs conduct a trial to determine the safety and effectiveness of a new drug/device, evaluate a new approach to treat a disease or already in practice procedures so enhance their application, ease and lessen certain side effects and also determines the safety of a previously used drug/device in a population where it was not tested ever.<sup>17</sup>

Depending upon operational activities, some CTUs specialize in randomized controlled trials, cluster randomized trials, surgical trials, health services research. Others specialize in one disease type, whereas others are generic units. At large, the CTUs focus on specific phases and types of clinical trials. According to World Health Organization, there are four phases of a biomedical clinical trial that are conducted at CTUs namely the Phase-I, Phase-II, Phase-III and Phase-IV, each having its own procedural regulatory requirements. The establishment of CTUs in renowned medical and research institutions has set a precedent for excellence in clinical research.<sup>18</sup>

The Dr. Akbar Niazi Teaching Hospital (ANTH) is a 500-bedded leading tertiary care facility in Islamabad Capital Territory aiming to provide quality medical and health care services. ANTH took a significant leap forward by establishing a state-of-the-art CTU in 2023. The CTU site has been approved from the Drug Regulatory Authority of Pakistan (DRAP) to conduct Phase-III and Phase-IV clinical trials. The establishment of the CTU at ANTH reflects the dedication of the leadership for excellence in medical services and significant contribution in the progression of the field at national and international level. The CTU is a dedicated facility at ANTH with trained staff for clinical trials and clinical studies to be conducted with quality standards, minimizing the risk of bias, ensuring data integrity, and prioritizing participants' safety. The mission of the Clinical Trials Unit (CTU) is to create an environment for state-of-the-art clinical trials to promote integration into the

greater translational development of treatments of various diseases.

The CTU team is committed to boost research productivity and quality at ANTH. The newly established certified facility is ambitious with open doors to all clinical study related sponsors, research organizations, pharmaceutical industry and CRO's (Contract Research Organizations) to avail this site for clinical trials. ANTH's CTU facility is spearheaded by the experience of well renowned clinicians and medical staff. The CTU is looking forward to excel the research culture in the organization and share their part in the growth of medical and clinical sciences. By conducting clinical trials and research activities by involving the experts of the field, CTU is poised to emerge as a premier destination for clinical trials in the region. As the scientific community continues to navigate the complexities of clinical research, the CTU at ANTH stands ready to facilitate the development of innovative treatments, shaping the future of healthcare for generations to come.

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