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Different Names of Participants in Phase I Clinical Trials

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ABSTRACT

Background: Clinical trials contribute to the generation of new knowledge and can lead to the discovery of novel treatments. By introducing more effective therapies, they can improve patients' quality of life and reduce the complications of diseases. For searching scientific resources in this context, one should focus on appropriate keywords, identify synonyms, related phrases, and academic terms in this field to expand the scope of the search. The first phase of clinical trials is the initial step in evaluating an investigational drug product in humans.

Conclusion: In this review, given the importance of Phase I clinical trials, we first address the different and common names of Phase I clinical trials and then provide examples of synonyms for "study participants." It is hoped that researchers can, by identifying synonyms and related academic phrases, more quickly and accurately find relevant scientific resources and produce more precise and clear scientific writing.

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Introduction

A clinical trial is a research study conducted on human subjects (volunteers) to evaluate the efficacy and safety of a new treatment method (such as a drug, vaccine, medical device, surgical procedure, or diet) in comparison to the best available treatment or a placebo.

In simple terms, it is the final and most critical stage before a new treatment is introduced to the market. The ultimate goal is to ensure that the new treatment is both safe and effective (1).

An Overview of Phase I Clinical Trials

Clinical trials are typically divided into several main phases (Phase I, II, III, IV), with each phase pursuing a specific objective. Phase 1 focuses on safety, Phase 2 on preliminary efficacy, Phase 3 on definitive effectiveness, and Phase 4 on post-market monitoring. These stages outline the development path of a treatment from the laboratory to the community (Table 1).

The primary objective of Phase I clinical trials is to evaluate the safety of the investigational drug product in healthy volunteers (1).

The number of participants, depending on the study, is usually less than 50 people. In this phase, pharmacodynamics and pharmacokinetic effects are evaluated (2).

Various keywords are used to describe this phase. The most common term is "Phase I" with numeric notation, such as in the study conducted by Essink and colleagues in 2023 titled "The safety and immunogenicity of two Zika virus mRNA vaccine candidates in healthy flavivirus baseline seropositive and seronegative adults: the results of two randomized, placebo-controlled, dose-ranging, phase 1 clinical trials (3).

The phrase "Phase I" using Roman numerals is also frequently used, such as in the study conducted by Holmes and colleagues in 2008 titled "Long-term effects of Aβ42 immunisation in Alzheimer's disease: follow-up of a randomised, placebo-controlled phase I trial (4).

Subdivisions: Phase Ia and Phase Ib

Phase I clinical trials are conventionally subdivided into distinct stages, primarily Phase Ia and Phase Ib, based on their specific study design and objectives. This segmentation allows for a systematic, dose-escalation approach to initially characterize the safety and tolerability profile of a new investigational product.

Phase Ia, often referred to as the Single Ascending Dose (SAD) segment, is designed to establish the initial safety and tolerability parameters. In this phase, small cohorts of subjects receive a single dose of the drug. Following each administration, intensive safety monitoring is conducted. If the dose is well-tolerated, the subsequent cohort receives a higher single dose, following a predefined dose-escalation scheme. This process continues until the Maximum Tolerated Dose (MTD)—the highest dose at which the drug does not cause unacceptable side effects—is identified.

Phase Ib, or the Multiple Ascending Dose (MAD) segment, is typically initiated after the preliminary safety of single doses has been established. This phase aims to evaluate the safety, tolerability, and pharmacokinetics of the drug when administered repeatedly. Subjects receive the drug multiple times (e.g., daily for a week or two) at dose levels at or below the MTD determined in the SAD phase. The Ib design is critical for assessing drug accumulation, establishing a steady-state concentration, and understanding the safety profile under a dosing regimen more reflective of intended clinical use. This phased architecture within Phase I ensures a rigorous and ethical foundation for the subsequent evaluation of a drug's efficacy in patient populations during Phase II trials (5).

The project by Hua Xu and colleagues in 2023, titled "A phase 1a dose-escalation, multicenter trial of anti-claudin 18.2 antibody drug conjugate CMG901 in patients with resistant/refractory solid tumors, used the phrase "numeric Phase 1a" (6).

The project by Wang and colleagues in 2024, titled "Preliminary Evaluation of the Safety and

Immunogenicity of a Novel Protein-Based Pneumococcal Vaccine in Healthy Adults Aged 18–49: A Phase Ia Randomized, Double Blind, Placebo-Controlled Clinical Study," used the phrase "Roman Phase Ia" (7).

In Phase Ib, volunteers receive multiple ascending doses(5). The Phase I study conducted by Bruss and colleagues in 2021 was carried out in two stages: SAD phase followed by MAD phase (8).

The project by Fukuoka and colleagues in 2020, titled "Regorafenib Plus Nivolumab in Patients with Advanced Gastric or Colorectal Cancer: An Open-Label, Dose-Escalation, and Dose-Expansion Phase Ib Trial (REGONIVO, EPOC1603)," used the phrase "Roman Phase Ib" (9).

The project by van der Ree and colleagues in 2017, titled "Safety, tolerability, and antiviral effect of RG-101 in patients with chronic hepatitis C: a phase 1B, double-blind, randomised controlled trial," used the phrase "numeric Phase 1B" (10).

In some projects, Phases Ia and Ib are conducted simultaneously. For example, the project by Kim and colleagues in 2023 titled "A Novel PI3K γ/δ and DNA-PK Triple Inhibitor, BR101801, for r/r PTCL: A Phase 1a/b, Multi-Center, Open-Label Clinical Trial" used the phrase "numeric Phase 1a/b" (11).

The project by Bang and colleagues in 2020, titled "Ramucirumab and durvalumab for previously treated, advanced non–small-cell lung cancer, gastric/gastro-oesophageal junction adenocarcinoma, or hepatocellular carcinoma: An open-label, phase Ia/b study (JVDJ)," used the phrase "Roman Phase Ia/b" (12).

Since it is the initial stage for testing an investigational drug product in humans, it is also referred to as the "First-in-Human" phase. For example, the study conducted by Ishihara and colleagues in 2020 titled "First-in-human phase I clinical trial of the NY-ESO-1 protein cancer vaccine with NOD2 and TLR9 stimulants in patients with NY-ESO-1-expressing refractory solid tumors (13).

In some articles, where the target group consisted only of males, Phase I was referred to as "First-in-Man." For example, in the study conducted by YAP and colleagues in 2011, the term "First-in-Man" was used to refer to Phase I clinical trials (Table 2) (14).

Terminology for Study Participants

Individuals who participate in the study, undergo interventions, and whose results and outcomes are evaluated are referred to as subjects. In some articles, the term "subject" is used(15), while in others, they are referred to as "experimental participants" (16, 17).

In Phase I clinical trial studies, since participants are generally healthy and not patients, they are referred to as Healthy Volunteers(18). These participants may also be termed as Healthy Adult Participants (19), Healthy Adult Subjects(20), Healthy Subjects(21), Healthy Male Participants (22), Healthy People(23), Healthy Men and Women (24), Healthy Female Participants(25), Healthy Males (26), Healthy Adult Male Subjects (27), or simply Healthy Participants (28).

In some studies, race and nationality are taken into account, such as Healthy Male Japanese Study Participants (29) or Healthy Chinese Volunteers (30). However, in some Phase I studies, participants are not healthy. For example, they may have mental illness, AIDS, tumors, cancer, etc., such as A Study of GFH018 in Patients with Advanced Solid Tumors(31), where intervention was conducted on 50 individuals with advanced solid tumors.

Similarly, A Study of MK-8189 in Participants with Schizophrenia (MK-8189-014) (32) involved evaluations performed on 53 participants with schizophrenia. In studies where participants are not healthy, such as in Phases II, III, and IV, the term "patient" is used. For instance, Safety, Tolerability, Pharmacokinetic Characteristics and Preliminary Efficacy of TNP-2092 Capsules in Liver Cirrhosis Patients with Hyper ammonia (33-35).

Table 1. Phases of clinical trial studies.

Clinical Trial Phase	Type of Study
Phase 1	Non therapeutic trial
Phase 2	Exploratory trial
Phase 3	Pre marketing trial
Phase 4	Post approval study

Table 2. Various names for phase i clinical trial studies.

Name	Title Article	References
Phase 1	The safety and immunogenicity of two Zika virus mRNA vaccine candidates in healthy flavivirus baseline seropositive and seronegative adults: the results of two randomized, placebo-controlled, dose-ranging, **phase 1** clinical trials	(3)
Phase I	Low-dose suramin in autism spectrum disorder: a small, **phase I**/II, randomized clinical trial	(44)
Phase 1a	A **phase 1a** dose-escalation, multicenter trial of anti-claudin 18.2 antibody drug conjugate CMG901 in patients with resistant/refractory solid tumors.	(6)
Phase Ia	Preliminary Evaluation of the Safety and Immunogenicity of a Novel Protein-Based Pneumococcal Vaccine in Healthy Adults Aged 18–49: A **Phase Ia** Randomized, Double Blind, Placebo-Controlled Clinical Study	(7)
Phase 1b	Safety, tolerability, and antiviral effect of RG-101 in patients with chronic hepatitis C: a **phase 1B**, double-blind, randomized controlled trial	(10)
Phase I b	Regorafenib Plus Nivolumab in Patients with Advanced Gastric or Colorectal Cancer: An Open-Label, Dose-Escalation, and Dose-Expansion **Phase Ib** Trial (REGONIVO, EPOC1603)	(9)
Phase1 a/b	A Novel PI3K γ/δ and DNA-PK Triple Inhibitor, BR101801, for r/r PTCL: A **Phase 1a/b**, Multi-Center, Open-Label Clinical Trial	(11)
Phase I a/b	Ramucirumab and durvalumab for previously treated, advanced non-small-cell lung cancer, gastric/gastro-oesophageal junction adenocarcinoma, or hepatocellular carcinoma: An open-label, **phase Ia/b** study (JVDJ)	(12)
FIH	A **first-in-human**, open-label Phase 1b and a randomized, double-blind Phase 2a clinical trial in recent-onset type 1 diabetes with AG019 as monotherapy and in combination with teplizumab	(45)
	First-in-human phase I clinical trial of the NY-ESO-1 protein cancer vaccine with NOD2 and TLR9 stimulants in patients with NY-ESO-1-expressing refractory solid tumors	(13)
FIM	KH176 under development for rare mitochondrial disease: a **first in man** randomized controlled clinical trial in healthy male volunteers	(46)
	First-in-Man Clinical Trial of the Oral Pan-AKT Inhibitor MK-2206 in Patients with Advanced Solid Tumors	(14)

Table 3. Various names of participants in phase i clinical trial studies.

Name	Article Title	References
Healthy Volunteers	Effects of a short-term intervention with a Paleolithic diet in healthy volunteers	(37)
	A Phase 1 Single-Ascending-Dose Trial in Healthy Volunteers to Evaluate the Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Intravenous PNT001, a Novel Mid-domain Tau Antibody Targeting cis-pT231 Tau	(18)
Subject	Umbilical cord mesenchyme stem cells for COVID-19 acute respiratory distress syndrome: A double-blind, phase 1/2a, randomized controlled trial	(15)
	Safety and immunogenicity of the recombinant BCG vaccine VPM1002 in a phase 1 open-label randomized clinical trial	(38)
Trial Participants	Impact of Baseline Nutrition and Exercise Status on Toxicity and Outcomes in Phase I and II Oncology Clinical Trial Participants	(16)
	Clinical Pattern of Tolvaptan-Associated Liver Injury in Trial Participants with Autosomal Dominant Polycystic Kidney Disease (ADPKD): An Analysis of Pivotal Clinical Trials	(17)
Healthy Adult Participants	Study of ALXN1820 in Healthy Adult Participants Agave Inulin Supplementation Affects the Fecal	(39)
	Microbiota of Healthy Adults Participating in a Randomized, Double-Blind, Placebo-Controlled, Crossover Trial	(19)
Healthy Adult Subjects	Clinical Pharmacology Study of Oral Edaravone in Healthy Adult Subjects (Food Effect Study)	(40)
Healthy Subjects	A Study Assessing the Safety and Tolerability of LY03020 in Chinese Healthy Subjects	(41)
Healthy Male Participants	Study to Assess Absolute Bioavailability (ABA) of TAK-906 and to Characterize Mass Balance, Pharmacokinetics (PK), Metabolism, and Excretion of [14C]-TAK-906 in Healthy Male Participants	(42)
Healthy People	A Study in Healthy People to Test Whether BI 730357 Affects How 4 Other Medicines (Rosuvastatin, Digoxin, Metformin, and Furosemide) Are Taken up in the Body	(23)
Healthy Men and Women	A Study in Healthy Men and Women Who Are Either Between 18 - 45 Years or Between 65 - 80 Years to Test How Different Doses of BI 474121 Are Tolerated	(24)
Healthy Female Participants	A Study of the Effect of Tirzepatide on How the Body Handles Birth Control Pills in Healthy Female Participants	(25)
Healthy Males	The Effect of Moderate CYP3A Inducer Rifabutin on the Pharmacokinetics of Zanubrutinib in Healthy Males	(26)
Healthy Male Japanese	A Study to Assess the Bioequivalence Between Brivaracetam Tablet and Dry Syrup in Healthy Male Japanese Study Participants	(29)

Study Participants		
Healthy Chinese Volunteers	A Trial in Healthy Chinese Volunteers to Test How Different Doses of BI 655130 Are Taken up in the Body	(30)
Healthy Adult Male Subjects	Study to Assess the Absorption, Metabolism, Excretion, and Mass Balance of CT1812 in Healthy Adult Male Subjects (COG0108)	(27)
Healthy Participants	Safety, Tolerability, and Pharmacokinetics of XXB750 in Healthy Participants	(43)

A subject in a clinical trial is not necessarily a patient, but a patient in a clinical trial is a subject (Table 3) (36).

Clinical trials represent the cornerstone of evidence-based medicine, serving as the critical pathway through which novel therapeutic interventions are rigorously evaluated and validated. The results generated from these systematic investigations are instrumental in the development, refinement, and optimization of treatment protocols, ultimately identifying the most efficacious and safe methods for disease management. By establishing a structured framework for testing hypotheses in human populations, clinical trials facilitate the rapid translation of groundbreaking discoveries from the laboratory bench to the patient's bedside, thereby making innovative treatments available to those in need. Furthermore, these studies are designed to address pivotal questions in medical science, contributing significantly to a more profound and nuanced understanding of disease pathophysiology, mechanisms of drug action, and the overall risk-benefit profile of new therapies.

Conclsuion

Given the foundational importance of Phase I clinical trials, which constitute the initial evaluation of an investigational drug product in humans, this review provides a comprehensive lexical analysis. We will first delineate the various nomenclatures associated with Phase I trials themselves. Subsequently, we will conduct a detailed examination of the synonymous terms and academic phrases used to describe the participants in these early-stage studies, commonly referred to as "subjects" or "volunteers." The objective of this synthesis is to equip researchers, clinical investigators, and medical writers with a robust lexical toolkit. By mastering this specialized terminology, scholars can conduct more efficient and comprehensive literature searches, enhance the precision of their scientific writing, and ensure their work aligns with the evolving standards of ethical and professional discourse in clinical research. This, in turn, accelerates the discovery process and fosters clearer communication within the global scientific community.

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Conflict of interest

None decleared.

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