

Phase 1 Clinical Trial

The UKCRC evaluates CTUs in the UK and they may be given either Full or Provisional CTU registration status. All Registered CTUs are required to provide evidence that their work is of high quality by demonstrating (1) experience of coordinating multi-centre randomised controlled trials or other well-designed studies, (2) a presence of a core team of expert staff to develop studies, (3) a presence of robust quality assurance systems and processes to meet appropriate regulations and legislation, and (4) evidence of longer-term viability of capacity for trials coordination and the development/maintenance of a trials portfolio. 7efc075683 == Media and music == 7efc075683 In response, the European Council endorsed a Programme for Action on HIV/AIDS, malaria and tuberculosis in May 2001. The Council of the EU and the European Parliament jointly adopted the founding decision establishing EDCTP in June 2003, under Article 169 of the EC Treaty (later renumbered Article 185 of the Treaty on the Functioning of the European... 7efc075683 Phase 1 (Saga album), 1998 7efc075683 Depending on product type and development stage, investigators initially enroll volunteers or patients into small pilot studies, and subsequently conduct progressively larger scale comparative studies. Clinical trials can vary in size and cost, and they can involve a single research center or multiple centers, in one country or in multiple countries. Clinical study design aims to ensure the scientific validity and reproducibility of the results... 7efc075683 PhaseOne, Australian DJ and electronic music producer 7efc075683 == Description == 7efc075683 == Description == 7efc075683 == Mission == 7efc075683 The treatments being investigated are remdesivir, lopinavir/ritonavir combined, lopinavir/ritonavir combined with interferon-beta, and hydroxychloroquine or chloroquine. Hydroxychloroquine or chloroquine investigation was discontinued in June 2020 due to concluding that it provided no benefit. 7efc075683 If the drug successfully passes through Phases I, II, and III, it will usually be approved by the national regulatory authority for use in the general population. Phase IV trials are 'post-marketing' or 'surveillance' studies conducted to monitor safety over several years. 7efc075683

Solidarity trial The trial was announced 18 March 2020, and as of 6 August 2021, 12,000 patients in 30 countries had been recruited to participate in the trial. The Solidarity trial for treatments is a multinational Phase III-IV clinical trial organized by the World Health Organization (WHO) and partners to compare The Solidarity trial for treatments is a multinational Phase III-IV clinical trial organized by the World Health Organization (WHO) and partners to compare four untested treatments for hospitalized people with severe COVID-19 illness 7efc075683

Marvel Cinematic Universe: Phase One, six American superhero films from 2008–2012 7efc075683 Candidate vaccines were developed in the United States and the United Kingdom during 2003 for protection against the strain that was isolated from humans

in Hong Kong in February 2003 but the 2003 strain died out in 2004 making the vaccine of little use. In April 2004, WHO made an H5N1 prototype seed strain available to manufacturers. In August 2006, WHO changed the prototype strains and now offers three new prototype strains which represent three of the six subclades of the clade 2 virus which have been responsible for many of the human cases that have occurred since 2005. 7efc075683 == United Kingdom == 7efc075683

Phase 1 producer Phase I clinical trials, the first of the phases of clinical research Canadian Phase I, a powered parachute design Phase I metabolism, Phase I reaction Phase 1, Phase I or Phase One may refer to: 7efc075683

Clinical research is different from clinical practice: in clinical practice, established treatments are used to improve the condition of a person, while in clinical research, evidence is collected under rigorous study conditions on groups of people to determine the efficacy and safety of a treatment. 7efc075683 Phase One, renamed Bloodwork (film), a 2012 American-Canadian thriller 7efc075683

AIDS Clinical Trials Group The ACTG is funded by the Department of Health and Human Services, National Institutes of Health through the National Institute of Allergy and Infectious Diseases. The AIDS Clinical Trials Group (ACTG) network is one of the largest HIV clinical trials organizations in the world, playing a major role in setting standards The AIDS Clinical Trials Group (ACTG) network is one of the largest HIV clinical trials organizations in the world, playing a major role in setting standards of care for HIV infection and opportunistic diseases related to HIV and AIDS in the United States and the developing world. The ACTG is composed of, and directed by, leading clinical scientists in HIV/AIDS therapeutic research 7efc075683

== Background and rationale == 7efc075683

European and Developing Countries Clinical Trials Partnership Countries Clinical Trials Partnership (EDCTP) is a long-running initiative linking European and African countries to fund and coordinate clinical research The European and Developing Countries Clinical Trials Partnership (EDCTP) is a long-running initiative linking European and African countries to fund and coordinate clinical research on infectious diseases in sub-Saharan Africa. The current phase, known as Global Health EDCTP3, has operated as a European Union Joint Undertaking since 2021. Since its establishment in 2003, the programme has operated across three successive phases, each with a distinct legal form and expanded scope 7efc075683

== Solidarity trial for treatment candidates == 7efc075683 In the early 2000s, the European Commission identified a significant gap between the scale of research investment directed at infectious diseases prevalent in wealthy countries and the comparatively small resources devoted to diseases disproportionately affecting sub-Saharan Africa; particularly HIV/AIDS, tuberculosis, and

malaria. 7efc075683

Clinical research four phases in research subjects that give consent to participate in the clinical trials. These research procedures are designed for the prevention, treatment, diagnosis or understanding of disease symptoms. Clinical research associate Clinical research ethics Clinical trial Clinical research is a branch of medical research that involves people and aims to determine the effectiveness (efficacy) and safety of medications, devices, diagnostic products, and treatment regimens intended for improving human health 7efc075683

Clinical trials testing potential medical products are commonly classified into four phases. The drug development process will normally proceed through all four phases over many years. When expressed specifically, a clinical trial phase is capitalized both in name and Roman numeral, such as "Phase I" clinical trial. 7efc075683 The National Institute of Allergy and Infectious Diseases (NIAID) awarded H5N1 vaccine contracts to Aventis Pasteur (now Sanofi Pasteur) of Swiftwater, Pennsylvania, and to Chiron Corporation of Emeryville, California. Each manufacturer is using established techniques in which the virus is grown in eggs... 7efc075683 The term "clinical research" refers to the entire process of studying and writing about a drug, a medical device or a form of treatment, which includes conducting interventional studies (clinical trials) or observational studies on human participants. Clinical research can cover any medical method or product from its inception in the lab to its introduction to the consumer market and beyond. Once the promising candidate or the molecule is identified in the lab, it is subjected to pre-clinical studies or animal studies... 7efc075683

Phases of clinical research [failed verification] If the drug The phases of clinical research are the stages in which scientists conduct experiments with a health intervention to obtain sufficient evidence for a process considered effective as a medical treatment. For drug development, the clinical phases start with testing for drug safety in a few human subjects, then expand to many study participants (potentially tens of thousands) to determine if the treatment is effective. Clinical research is conducted on drug candidates, vaccine candidates, new medical devices, and new diagnostic assays. specifically, a clinical trial phase is capitalized both in name and Roman numeral, such as "Phase I" clinical trial 7efc075683

The trial intends to rapidly assess thousands of COVID-19 infected people for the potential efficacy of existing antiviral and anti-inflammatory agents not yet evaluated specifically for COVID-19 illness, a process called "repurposing" or "repositioning" an already-approved drug for a... 7efc075683 == History == 7efc075683

Clinical trial Clinical trials are prospective biomedical or behavioral research studies on human participants designed to answer specific questions about biomedical Clinical trials are prospective biomedical or behavioral research studies on human participants

designed to answer specific questions about biomedical or behavioral interventions, including new treatments (such as novel vaccines, drugs, dietary choices, dietary supplements, and medical devices) and known interventions that warrant further study and comparison. These authorities are responsible for vetting the risk/benefit ratio of the trial—their approval does not mean the therapy is "safe" or effective, only that the trial may be conducted. Clinical trials generate data on dosage, safety and efficacy. They are conducted only after they have received health authority/ethics committee approval in the country where approval of the therapy is sought 7efc075683

Phase One (Art Ensemble of Chicago album), 1971 7efc075683 In May, the WHO announced an international coalition for simultaneously developing several candidate vaccines to prevent COVID-19 disease, calling this effort the Solidarity trial for vaccines. 7efc075683 Through innovative studies of the treatment of HIV-1 infection and its complications, ACTG research focuses on: 7efc075683

In silico clinical trials Phase 3 involves An in silico clinical trial, also known as a virtual clinical trial, is an individualized computer simulation used in the development or regulatory evaluation of a medicinal product, device, or intervention. Clinical trials are often divided into four phases. propose that clinical trials test whether the product should be made available for humans. While completely simulated clinical trials are not feasible with current technology and understanding of biology, its development would be expected to have major benefits over current in vivo clinical trials, and research on it is being pursued 7efc075683

The term in silico indicates any use of computers in clinical trials, even if limited to management of clinical information in a database. 7efc075683 == Current status of H5N1 candidate vaccines == 7efc075683

H5N1 vaccine clinical trials They H5N1 clinical trials are clinical trials concerning H5N1 vaccines, which are intended to provide immunization to influenza A virus subtype H5N1. H5N1 clinical trials are clinical trials concerning H5N1 vaccines, which are intended to provide immunization to influenza A virus subtype H5N1. They are intended to discover pharmacological effects and identify any adverse reactions the vaccines may achieve in humans 7efc075683

Clinical trials unit Some CTUs focus on specific phases and types of clinical trials; others conduct all phases and types of trial. Some CTUs specialise in different methodologies, such as randomised controlled trials, cluster randomised trials, surgical trials, and health services research. Some specialise in one disease type, whereas others are generic units. units. The UKCRC evaluates CTUs in the UK Clinical trials units (CTU) are specialised biomedical research units which design, centrally coordinate and analyse clinical trials and other studies. Some CTUs focus on specific phases and types of clinical trials; others conduct all phases and types of trial 7efc075683

Provisional CTUs tend to be newer and evolving CTUs and... 7efc075683

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