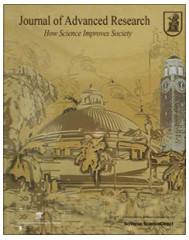
Journal of Advanced Research (2016) 7, 37–45

Cairo University

Journal of Advanced Research



ORIGINAL ARTICLE

The Egyptian clinical trials' registry profile: Analysis of three trial registries (International Clinical Trials Registry Platform, Pan-African Clinical Trials Registry and clinicaltrials.gov)

Ahmed A. Zeeneldin [a,*], **Fatma M. Taha** [b]

[a] *Medical Oncology/Hematology, National Cancer Institute, Cairo University, Cairo, Egypt*
[b] *Unit of Biochemistry and Molecular Biology, the Medical Biochemistry Department, Faculty of Medicine, Cairo University, Cairo, Egypt*

ARTICLE INFO

Article history:
Received 5 May 2014
Received in revised form 21 November 2014
Accepted 11 January 2015
Available online 17 January 2015

Keywords:
Clinical trial registry
Design
Interventional studies
Observational studies
Egypt

ABSTRACT

Registering clinical trials (CTs) in public domains enhances transparency, increases trust in research, improves participation and safeguards against publication bias. This work was done to study the profile of clinical research in Egypt in three CT registries with different scopes: the WHO International CT Registry Platform (ICTRP), the continental Pan-African CT Registry (PACTR) and the US clinicaltrials.gov (CTGR). In March 2014, ICTRP, PACTR and CTGR were searched for clinical studies conducted in Egypt. It was found that the number of studies conducted in Egypt (percentage) was 686 (0.30%) in ICTRP, 56 (11.3%) in PACTR and 548 (0.34%) in CTGR. Most studies were performed in universities and sponsored by university/organization, industry or individual researchers. Inclusion of adults from both genders predominated. The median number of participants per study in the three registries ranged between 63 and 155. The conditions researched differed among the three registries and study purpose was mostly treatment followed by prevention. Endpoints were mostly efficacy followed by safety. Observational:Interventional studies (i.e. clinical trials) represented 15.5%:84.5% in ICTRP, 0%:100% in PACTR and 16.4%:83.6% in CTGR. Most interventions were drugs or procedures. Observational studies were mostly prospective and cohort studies. Most CTs were phase 3 and tested drugs or procedures. Parallel group assignment and random allocation predominated. Blinding was implemented in many of trials and was mostly double-blind. We

* Corresponding author. Tel.: +20 1111 000 943; fax: +20 253 28286.
E-mail address: ahmed.zeeneldin@nci.cu.edu.eg (A.A. Zeeneldin).

Peer review under responsibility of Cairo University.

http://dx.doi.org/10.1016/j.jare.2015.01.003

conclude that CTs from Egypt in trial registries are apparently low and do not accurately reflect clinical research conducted in Egypt or its potential. Development of an Egyptian CT registry is eagerly needed. Registering all Egyptian CTs in public domains is highly recommended.

Introduction

Clinical research is the type of scientific research that involves human subjects and includes patient-oriented research, epidemiologic and behavioral studies, and outcomes research and health services research [1]. Clinical studies evaluate the effect of interventions or exposures on biomedical or health-related outcomes that include prevention, diagnosis and treatment of diseases. They are broadly classified into observational and interventional studies. Clinical trials (CTs) or interventional studies are clinical studies in which participants are assigned by researchers/investigators to receive one or more interventions to assess their safety and efficacy. In observational studies, participants are not assigned to interventions by the investigators. Clinical trials are classically classified into 5 phases (0–4). Phase 0 studies are exploratory studies involving very limited human exposure to an investigational new drug (IND) for example screening studies and microdose studies [2]. The primary aims of phase 0 studies are identifying, early in the process of drug development, viable candidates and eliminating those lacking promise with a potential reduction in costs and time-to-first-in-human testing. The endpoints include evaluation of analogs for lead selection, modulation of a molecular target in vivo, whole-body imaging for tissue distribution/target binding affinity, and agent pharmacokinetics [*]. They are ethically acceptable [**]. Phase 1 studies aim to find out the drug's most frequent and serious adverse events and the drug metabolism and excretion. Phase 2 studies gather preliminary data on efficacy. Phase 3 studies gather more information about safety and effectiveness. The randomized controlled trial (RCT) is widely regarded as the gold standard for evaluating health care interventions. Phase 4 studies occur after marketing approval of a drug by authorities and aim to gather additional information about a drug's safety, efficacy and optimal use [2].

Participation in clinical trials is a voluntary action after subjects are fully informed of the research and give their consent [3]. Without participants, no CT can conclude. Clinical trial registries (CTRs) facilitate the prospective registration of CTs and the accessibility of their information by patients, physicians, researchers and other interested stakeholders. This enhances transparency, increases participation in CTs and can eliminate publication bias that arises from publishing positive trial results more than the negative ones [4,5]. Some countries mandate CT registration; others do not ask for registration, but often strongly encourage it. CT registration is mandated or recommended by many laws and policies including U.S. Federal law, Declaration of Helsinki, European Union Clinical Trials Directive, WHO Clinical Trials Directive, International Committee of Medical Journal Editors (ICMJE) [6]. Currently, there are many CTRs with a scale being global (e.g. WHO International Clinical Trials Registry Platform [ICTRP]) [4], continental/regional (e.g. EU Clinical Trials Register [EU-CTR] [7] and Pan-African Clinical Trials Registry [PACTR] [8]), country-specific (e.g. US clinicaltrials.gov [6]) or companies and associations (e.g. International Federation of Pharmaceutical Manufacturers Associations [IFPMA]) [9].

ClinicalTrials.gov registry (CTGR) is a trial registry hosted by the US National Institute of Health (NIH). It is a governmental website. In February 2000, it was made available to the public as a registry of clinical trials information on federally and privately funded trials conducted under investigational new drug (IND) applications to test the effectiveness of experimental drugs for serious or life-threatening diseases or conditions. In September 2008, more information on study participants and a summary of study outcomes, including adverse events were made available. By 17th of March 2014, CTGR contained 163,090 studies [10]. The idea of a global clinical trial registry rose in the year 2004. The WHO first established the requirements of CTRs and a trial registration data set. The focus then shifted to establishing the two key elements of the platform: the International Clinical Trials Registry Platform (the ICTRP Network) and a single point of access (the ICTRP Clinical Trials Search Portal (CTSP)). CTSP provides a single point of access for the identification of trials in many contributing registries. CTSP was launched in May 2007 and initially contained trial records provided by three CTRs: the Australian New Zealand Clinical Trials Registry (ANZCTR), CTGR and the International Standard Randomised Controlled Trial Number (ISRCTN) Registry. In addition to the above registries, the ICTRP Registry Network includes registries based in Brazil, China, Cuba, EU-CTR, Germany, India (CTRI), Iran, Korea, Japan, the Netherlands, PACTR, Sri Lanka, Thai and UK [11]. By 17th of March 2014, ICTRP contained 271,811 records for 229,638 trials [4].

In early 2007, the Pan-African Clinical Trials Registry (PACTR) was established by the South African Cochrane Centre, in partnership with the European and Developing Countries Clinical Trials Partnership and the Cochrane Infectious Disease Group. In the initial phase, PACTR registered trials in HIV/AIDS, tuberculosis and malaria to demonstrate proof of concept. Once established, the goal of PACTR is to become the registry of choice for any clinical trial conducted in Africa [8]. On 25th of September 2009, PACTR was officially launched as a member of the WHO Primary Registry Network in Abuja, Nigeria [12]. PACTR is presently the only African member of the WHO Network of Primary Registers and transfers all trial information to the WHO CTSP on a quarterly basis. As of 17th of March 2014, PACTR contains 300 trials [8].

The aim of this work is to study the profile of clinical trials in Egypt in three clinical trial registries with different scopes: the global ICTRP registry, the regional/continental PACTR registry and the US CTGR.