

Press Release

Clinical trials are the oxygen for the patient, but also for the country

Athens, 20 May 2015 – To mark the International Clinical Trials’ Day, a special session of the 2nd ATHENS HEALTH FORUM, held under the auspices of SFEE, was dedicated to **“Clinical research and innovative treatments in Greece: necessity or luxury?”**. Clinical research is a matter of fundamental value both for patients and for Greece. The new epidemiological profile that has emerged across Europe is characterised by an aging population and a rise in chronic diseases, which points to the need to have many more participants in clinical trials. Innovation and human resources are the two pillars on which clinical research must rest. Against this background, this day is an occasion to celebrate the contribution of thousands of participants in clinical trials, not only in our country but throughout Europe, thanks to whom significant progress has been made in many diseases, often translating into longer life expectancy, lower mortality rates in diseases such as HIV and cancer, and cures for diseases that until recently were incurable, such as Hepatitis C.

In his opening address, **the President of SFEE, Mr. Pascal Apostolides**, outlined the industry’s strategy, underlining the Association’s willingness to support with actions, expertise and new proposals the country’s efforts to exit from the troubles of the past few years and help Greece to become a competitive player in the field of pharmaceuticals and especially in attracting clinical trials. Clinical trials are the “oxygen” to the country’s human capital and economy. **Every time a clinical trial is approved, Greece is set to receive an inflow of about €250,000, which, taking into account the published fiscal multipliers, adds to GDP a net amount of well above €500,000 per project** (data from a study of the National School of Public Health).

The pharmaceutical industry intends to invest further in clinical research, thereby fostering economic growth and social welfare in Greece, more than quadrupling its research budget within 2-3 years. However, Mr. Apostolides stressed that this crucially presupposes *“encouragement and incentives to the industry’s investment projects as well as effective solutions to the dysfunctions that have so far refrained companies from undertaking further investment in the country, e.g. in production and clinical trials, which can tangibly and immediately generate income and jobs, thereby contributing to much-needed*

growth in our country, as well as to the implementation of the health policy currently being redesigned”.

In his turn, **the Secretary General of Public Health, Mr. I. Baskozos**, emphasised the comparative advantage that our country will have if it can harness its high-quality scientific human resources towards more research and innovation, while he also stressed the **importance of cooperation among all stakeholders** in order to help Greece to change its **growth model** and move on to **a new era of a skills-based economy** geared towards research, innovation and development.

Regarding clinical trials, **SFEE announced the establishment of a special Vice President function and Committee for Clinical Trials, with the task to coordinate the initiatives of the industry with the involvement of all relevant institutional bodies for the purpose of encouraging clinical trials in our country.** The Committee will serve as a forum for an exchange of knowledge and information about the steps made in innovative methods and treatments that are expected to benefit thousands of patients. In this respect, Mr. Spyros Filiotis, SFEE’s Vice President responsible for clinical trials, indicated that it is a strategic goal “to make fully understood that clinical trials are the ‘big investment’ that society wants, cost nothing to the State, reinforce and do not compromise social goods, and that the companies are here to make this happen”. Mr. Filiotis also noted that, apart from the obvious benefits in the area of pharmaceuticals, it would be meaningful to make clinical trials a major priority not only for the industry but also for our country.

In particular, the benefits of clinical trials include the following:

- **for patients**, early access to innovative treatments that make breakthroughs in serious diseases and improve life expectancy;
- **for healthcare professionals**, introduction of new medicines in the therapeutic arsenal and more options from which to choose the appropriate treatment;
- **for researchers**, establishment of an environment favouring prestigious publications and international collaborations;
- **for the National Health System**, transfer of research know-how, better management skills and equipment;

• **for the national economy**, significant capital inflows to Greece, higher employment and job creation.

A panel discussion followed, which was moderated by **Dr. B. Baroutsou**, Internal Medicine Specialist, Coordinator of the SFEE Committee for Clinical Trials, Chief Medical Officer at Novartis Hellas, together with the journalist **M. Kefalogiannis**. Participants in the discussion were Messrs **M. Karamouzis**, Assistant Professor of the School of Medicine and member of the National Ethics Committee; **Professor Ath. Skoutelis**, Coordinating Director, 5th Department of Internal Medicine and Infectious Diseases, Evangelismos Hospital, Member of the National Committee of Ethics and Clinical Trials; **Ch. Antonopoulos**, MD, PhD, Medical Director, Roche Hellas, Member of the SFEE Committee for Clinical Trials, and **Ms. K. Koutsogianni**, President, Crete Rheumatic Patients Association. As a general conclusion, the discussion highlighted the importance of clinical research for patients' access to innovative medicines, for the professional development of medical staff and for economic growth in the country.

Ms. Barbara Baroutsou, talking about the need to monitor clinical research activity, noted that: “Modern cutting-edge clinical research means biomedical progress, lower costs and shorter lead times for the development of new pharmaceutical agents, enabling citizens to have early access to all innovative medicines and take advantage of new treatment options as soon as possible. In effect, new original medicines and new treatments translate scientific advances into better public health – which is an essential building block of prosperity and social development – with the contribution of the scientific excellence of clinical researchers”.

Ms. Katerina Koutsogianni underlined the need to draw the State's attention to serious diseases and stressed the importance of decent care and patient access to all modern treatments. Moreover, Ms. Koutsogianni called for coordinated and systematic information to patients through patient associations and disclosure of clinical trial results according to WHO guidelines, which will help to dispel the myth that patients are guinea pigs and to stop demonising clinical trials. On his part, **Prof. Athanasios Skoutelis**, talking about the huge benefits of clinical trials and the associated capital inflows to the country, focused on their employment potential in terms of absorbing young unemployed scientists and generating income for many groups of workers. As he put it, *it is an honour and a privilege for the country and its doctors to have access to (expensive) medicines for free*,

especially at the current critical juncture". **Mr. Christos Antonopoulos** expressed his belief that *"clinical research is a driving force for a healthcare system and, by extension, for the economy of a country. Greece has a huge advantage in terms of excellent research staff. Nevertheless, it still lags behind other countries with similar populations, such as Belgium and Portugal, in attracting new clinical trials, and this is due to, among other things, the lack of a uniform framework (institutional and legal)"*. Mr. Antonopoulos also stressed the paramount importance of cooperation among all stakeholders (State, scientific community, pharmaceutical industry and patients) in order for the multiple benefits of clinical research to become visible in practice. **Mr. Michael Karamouzis** reaffirmed that the conduct of clinical trials is a necessity, not a luxury, and underlined the importance of dialogue and cooperation among all stakeholders and the activation of patient associations. According to 2014 data which he presented, 741 applications for clinical trials (new and modifications) were submitted for ethical review, of which 55-60% were in the fields of Hematology and Oncology. Finally, referring to the new European legislation aimed to cut red tape, Mr. Karamouzis said that the launch of an electronic clinical trials database and the participation of patient associations in National Ethics Committees are expected within 2016.

According to the data presented at the conference, clinical trials are expected to edge downwards in 2015, declining by 12%. In order to reverse this trend, a number of policy recommendations were made, aimed to speed up approval procedures and attract a larger number of clinical trials, with a focus on reducing red tape and ensuring systematic observance of the timelines for approval according to EU and national legislation. Participants called for synergies with other stakeholders for the transfer of know-how; a review of the necessary infrastructure; a better utilisation of Greece's scientific potential in clinical research; and the establishment of a Clinical Trial Register database, which will provide access to statistical data.