

Press Release

Clinical trials will give fresh impetus to public health and economic growth in our country

Athens, 22 May 2014 - The importance of clinical trials for citizens' welfare and for the national economy was the focus of an event held by SFEE at the Auditorium of the National School of Public Health to mark the **International Clinical Trials' Day**. The event, entitled "**Clinical trials in Greece: Why don't we speed up?**", was moderated by Mr Ioannis Kyriopoulos, Professor of Health Economics at the National School of Public Administration, and was honoured by the presence of the **Minister of Health, Mr. Adonis Georgiadis**, who reaffirmed that the government's first priority is to address the technical issues that have caused delays in clinical trials, while he also highlighted the need to resolve the problems and press ahead to tap Greece's high-quality scientific potential. For his part, the **President of the National Organisation for Medicines (EOF), Dr Dimitrios Lintzeris**, stated that clinical trials are a tool for advancing medical knowledge, patient care and economic growth and blamed the Greek mentality for the failure to reach an understanding among stakeholders, stressing that what is missing is the way to achieve the result. The **Secretary General for Public Health, Ms. Christina Papanikolaou**, stated among other things that: "Greece has all the credentials, with the excellent academic training of its researchers and the experience of its authorities, EOF committees and the National Ethics Committee in the evaluation, approval and monitoring of clinical trials".

In a brief address, the President of SFEE, **Mr. Konstantinos Frouzis**, stated: "Clinical research creates and maintains high-skill jobs and helps to import international knowhow into the Greek growth model. With appropriate financial, tax and investment incentives, as well as by liaising with universities and research, we can achieve a remarkable performance. However, our country is still not competitive as far as multinational programmes are concerned, mainly because of delays in the initiation and completion of clinical trials. Currently, the vision of achieving an annual income of more than 300 million from investment in clinical trials seems unrealistic. It is almost certain that income from clinical trials did not increase in 2013 after a weak 2012, while for 2014, judging from approvals, we should probably see even lower levels".

In closing, the President of SFEE called for cooperation among all stakeholders; as he characteristically said: "What is needed is close cooperation among all stakeholders in order to find collaborative solutions that will enable to exploit the country's potential and make it

a reliable European partner. The objective of SFEE and all its members companies is to promote Greece as a hub for clinical research of international calibre that will give fresh impetus to public health and the national economy”.

Ms. Barbara Baroutsou, Coordinator of the Medical Directors Committee of SFEE and Medical Director of SANOFI, drew attention to the need to monitor clinical research activity, stressing that: “Modern, cutting-edge clinical research means biomedical progress, lower costs and shorter lead times for the development of new pharmaceutical agents, hence citizens’ early and easy access to innovative medicines and the benefits of new therapeutic options. In effect, new original medicines and new treatments translate scientific advances into gains in public health, which is an essential building block of prosperity and social progress, brought about by the scientific excellence of clinical researchers”.

During the event, **Mr Kostas Athanasakis**, Research Associate of the Health Economics Department of the National School of Public Health, presented the results of a study conducted among SFEE member companies, entitled: “**A survey of clinical trials in Greece: new facts and figures**”. In comparison with 2010, the study finds some progress towards streamlining the approval process at the level of the National Ethics Committee (NEC), as well as unchanged participation rates across NHS hospitals and universities. The findings also suggest some decline in clinical trials activity between 2010 and 2012, as evidenced by a lower average budget per study (2010: €296,602, 2012: €218,555) and falling average numbers of participating patients and research centres per study.

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The survey was conducted among all members of SFEE (70 Greek and subsidiaries of multinational companies), of which 28.57% reported that they had engaged in clinical trials activity in 2012. The number of approved interventional studies by SFEE member companies for 2012 remains low, with only 70 new interventional clinical trials having been approved by the NEC. The total number of approved studies (initial approval) in Greece rose from an estimated 120 in 2010 to 138 in 2012; for 2013, it is estimated at 122, implying a drop of 12%. This number probably does not reflect Greece’s capabilities in terms of infrastructure, scientific competence and human capital, considering that, in the same period, the number of clinical trials in countries such as Belgium is more than triple that figure, and even countries with lower levels of know-how such as Romania record numbers as high as 200.

Clinical trials are the “oxygen” for the country’s human capital and economy. According to the study of the National School of Public Health, every time a clinical trial is approved, Greece is set to receive an inflow of about €250.000, which, taking account the published fiscal multipliers, adds to GDP a net amount of well above €500.000 per project. Nevertheless, it seems (until 2012 at least) that there is a lack of momentum. With a new

institutional framework and given the willingness of pharmaceutical companies and the declared intention of the authorities to support investment in research in Greece, the question “Why doesn’t Greece speed up?” remains crucial and urgently needs an answer. It is a national priority to find solutions.

A discussion on the findings of the study followed next, with the participation of Messrs **D. Lintzeris, President of EOF, A. Papavassiliou, Chairman of the NEC, V. Koutzamanis, Chief Executive, 1st Regional Health Authority of Attica, K. Syrigos, Professor of Medical Oncology of the Athens School of Medicine and Director of the Sotiria Hospital, Ch. Iatrou, Coordinator-Director of Nephrology Centre, General Hospital of Nikaia, Piraeus.** The discussants highlighted the benefits of clinical trials, which are manifold and refer to the following:

For patients:

- Early access to new treatments, especially for life-threatening diseases
- Better treatment of a wide range of conditions
- More therapeutic options
- Improved life expectancy
- Better quality of life

For health professionals:

- New medicines in the therapeutic arsenal
- Ability to choose the appropriate treatment for each case
- Answers to specific medical questions
- Deeper knowledge and understanding of various diseases
- More experience in the treatment of various diseases

For researchers:

- Higher validity of publications
- Promotion of Greek researchers and their teams
- International cooperation and extroversion
- More funding for basic, translational and independent academic research and related infrastructures (research laboratories and centres of excellence)
- Revenue for universities’ Special Accounts for Research Funds (ELKE)
- Additional income for researchers/doctors and prevention of brain drain

For the National Economy:

- Significant capital inflows to Greece
- Possibility of investment in healthcare structures
- Job creation, utilisation of scientific staff in specialised fields

For the National Health System:

- Transfer of research know-how
- Better management skills and equipment
- Inflow of revenue (15% of the clinical trial budget goes to hospitals and 5% goes to the special accounts for R&D funds of Regional Health Authorities) particularly to meet internship and residency needs.

Moreover, according to estimates from the Foundation for Economic and Industrial Research (FEIR), **every additional €10 million in investment by the industry adds a total of €22 million to GDP, generating additional government revenue of €5.18 million in the form of taxes and contributions and creating 436 new jobs.** The pharmaceutical industry has an overall impact of €7.5 billion (3.4%) on GDP; it adds 132,000 jobs and €400 million in taxes and contributions (source: FEIR); it intends to invest further in clinical research – thereby supporting economic growth and social progress in Greece –more than quadrupling research funds within 2-3 years. A key condition for achieving this target is a **National Strategy and Planning** geared towards attracting and retaining clinical trials in Greece.

The adoption of Joint Ministerial Decision 18910/2013 (Government Gazette B 390) was a very important step forward; unfortunately, however, obstacles remain, due to the fact that the decision has not been fully or universally implemented by the relevant stakeholders, and its provisions are often subject to overinterpretation or subjective evaluation and inconsistently complied with across NHS Hospitals, Regional Health Authorities, Universities, along with understaffing and lack of skills at the institutions responsible for the evaluation and approval of clinical trials. Ensuring central coordination across public administration in addressing operational/procedural issues, especially as regards the implementation of contracts with hospitals and Regional Health Authorities, would unlock more opportunities for cooperation and funding within the NHS.

This situation, compounded by the equally long delays in approving prices and compensation of new medicines over the past three years, is now a very serious reason why Greece is excluded from clinical trials activity: perceiving Greece as an unreliable and non-competitive option, companies cut back further on their clinical trials here. The result is of course that

opportunities are missed to exploit the high domestic scientific potential and use its reliability as leverage to attract and retain more clinical trials in Greece.

At a time when the country is targeting growth, this affects the eligibility of our country for research projects, causing clinical trials by SFEE member companies to fall by 12% between 2010 and 2012 and unemployment in the field of research to rise, and of course depriving the country of significant inflows of funds from abroad.

Attracting investment in clinical research can be supported significantly by cutting red tape, streamlining processes and systematically adhering to the timetable for the approval of clinical trials in accordance with EU and national legislation. A very positive role will also be played by closer cooperation between the National Ethics Committee, EOF, Regional Health Authorities, universities, hospitals and patient associations on issues of clinical trials, as well as systematic public consultation and meetings of stakeholders to jointly restore the conditions for attracting clinical trials. Similarly, there is a need to raise awareness in the society at large and among patients in particular about the multiple benefits of clinical trials, within the framework of EU law that allows, under certain requirements, the provision of information to the public about these issues.

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The **recommended actions** to ensure that clinical trials become a priority in the national agenda for economic growth and public health include the following:

1. Setting up a Special Secretariat at the Ministry of Health and a National Board for clinical trials with the participation of all stakeholders (academic researchers, EOF, Regional Health Authorities, hospital managements, universities, Ministry of Development, Ministry of Finance, industry and patient associations) entrusting with national planning regarding clinical trials; such board should operate at the Ministry of Health under a special secretary general (a technocrat appointed for a 5-year term).
2. Attracting and utilising research funds in universities (Special Account for Research Funds), hospitals, Regional Health Authorities (Special R&D Funds), as well as funding and staffing of research teams and infrastructures at the NHS and Universities.
3. Establishing incentives for researchers, e.g. by abolishing the ceiling on remuneration and supporting their income to encourage them to remain in Greece.
4. Using revenue from clinical trials dues received in the context of interventional studies (estimated at at €5.4 million annually) for the staffing of research departments of EOF and National Ethics Committee and upgrading their operation.
5. Recognising clinical trials as scientific and technological research and establishing incentives for the relevant investment by the pharmaceutical industry, for example: tax

recognition of expenditure on clinical trials as R&D expenditure, job creation in the industry and a predictable business environment.

6. Universal and consistent compliance with the existing legal framework (Joint Ministerial Decision 18910/2013 - Government Gazette 390) and refinement of its provisions, including the necessary conditions for its implementation.

7. Creating an institutional framework in Greece for ethical review, approval and conduct of non-interventional studies as an integral part of clinical research.

8. Developing a legal framework to facilitate patient information campaigns and adopting a plan for raising awareness among patients, society and relevant stakeholders on the benefits of clinical trials for the economy and health.

9. Designing an effective investment support system to facilitate the use of the results of clinical trials for developing innovative products and services.

10. Funding by the private as well as by the broader public sector (e.g. EOF, research accounts of Regional Health Authorities, R&D funds of universities) of domestically developed clinical protocols in order to raise the research profile of the country.

11. Incorporating the principles of clinical trials into the undergraduate and graduate curricula of schools of health sciences.

12. Developing health technology assessment activity, which is inextricably linked with clinical trials activity.