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AICRO 2019 EVENT

Summary and disclosure document

The 6th annual event organized by AICRO, the Italian Association of CROs, took place in Milan on November 12, 2019.

AICRO represents, with its 24 members, the absolute majority of professionals employed in CROs in Italy, with an average number of employees for CROs associated with AICRO equal to 97.

With an aggregate investment estimated at 120 million Euros per year for employee labor costs alone, the associated CROs employ more than 2,000 employees, equal to one third of the research and development staff in Italy, which amount to about 6,000 according to the latest Farmindustria report.

Among the 2000 employees in AICRO, the CRA profession prevails largely with about 900 employees, the regulatory and start-up business is around 370 employees, the Project Managers / Team Leaders amount to about 360, the statistics / data management employees in aggregate are about 100, all other professions are covered by another 300 employees.

AICRO is one of the twelve ordinary members of EUCROF (European CRO Federation), which has a total of about 330 CROs associated with national associations.

The event, entitled "**Digital revolution in health and 'connection' with the future: a challenge for the professional figures involved",** had the patronage and support of several scientific societies involved in clinical research and an important feedback and support from the participants and the many stakeholders who took part in the work, an echo that has long resounded through social channels.

The 27 speakers strongly shared the determination to achieve the goal of maintaining an important role for Italy in clinical research, both sponsored and independent. This goal can be achieved by using the strong skills acquired and the enormous potential that the Italian research world has in this field: from the evolution of professional figures to the quality of our researchers.

One of the necessary conditions is undoubtedly the involvement of the institutions, with greater awareness and hopefully a more active and visible role, for example in view of the new challenges provided by the European Regulation 536/2014 on clinical trials, whose entry into force is now expected to be imminent.

The objective of this document is to align the attention of the Institutions and all other stakeholders on the issue of clinical research in Italy, which involves not only traditional professionals, i.e. pharmaceutical companies, CROs, researchers, but a much wider range of professionals and stakeholders. It's quite clear even observing the evolution in the field as to do quality research we create real multidisciplinary teams, which include, just to name a few, "cultural mediators", which ensure a proper process of signing informed consent, "data manager", able to use critically cutting-edge technological platforms, system builders able to develop the same, biostatisticians and managers of the so-called "big data" able to apply innovative methods, which allow to optimize the design of studies, the selection of centers and recruitment of patients and to enhance existing data.

These resources represent a very high potential within a country that wants to remain competitive with the rest of the world: clinical research has a significant impact on health supply, on the growth of investment and innovation in business and academia, on the development of new professions, on the high-tech sector and the development opportunities related to it, on the need to build a credible system capable of validating processes and products involving in a sensible and structured way especially the end users: **patients**. The current regulatory and methodological framework of clinical research is often not adequate to achieve this goal and complicates or even hinders the possibility of conducting clinical research in an agile and modern way and to grow the related sector. In fact, in many respects there is a restrictive and unnecessarily binding legislation when compared with other countries in Europe and the world.

In four interactive sessions the speakers shared with the audience their experiences showing how rich and multidisciplinary is the Italian professional heritage involved in clinical research, declined in scientific, technological, relational and ethical skills.

In the first session titled "**The key professions in clinical research**" exponents from the world of "Human Resources", independent research and pharmaceutical companies and CROs have analyzed the context and redefined the "vision" of the professional world related to clinical research, from the revisiting of old roles to the analysis and evolution of new ones, which include skills and experiences strongly linked to the ability to innovate. They testified how the sector requires highly defined professional figures, currently scarcely available, trained physicians and experienced research coordinators whose training is in some cases in highly qualified masters. It is desirable that the necessary notions and skills are also developed in university courses, creating professionals ready for interactive dialogue formulas, the logic of synergy, the attitude to change and the search for innovation.

<u>Outcome:</u> clinical research travels in parallel with the evolution of technology, as well as international regulations, new communication skills and the growth of multidisciplinary networks. As a result, the labour market of clinical research is extremely demanding in the search for qualified personnel. The reality shows that the opportunities in Italy do not reflect this expectation: there is a shortage of doctors and specialists, who probably lost confidence in the opportunities for professional realization in Italy, there are few and isolated virtuous realities in which professionals involved in clinical research are adequately considered and rewarded. Since there is no reference model, Italy risks losing skills and opportunities.

In the second session entitled "**The themes of digitization and modernization**" the speakers from the world of CROs, Ethics Committees, Universities and advanced technology companies have addressed more closely the topic of technological innovation with high potential in clinical research. They talked about digital technology as a possible therapeutic approach, as a source of clinical data (for example with wearable devices) as "siteless" patient management; topics closely related to the concept of interconnectivity. The state of the art of electronic informed consent with digital signature, of innovative experiments that consider, for example, the calculation of intake and caloric consumption, based on the recording of movement data from wearable devices. Last but not least, the experience of dematerialization of paper archives.

<u>Outcome:</u> in the face of a stimulating and evolving scenario, critical issues emerge related to the lack of clear indications from the institutional bodies in charge about the margins, feasibility/acceptability of the proposals. There are still many uncertainties related to the understanding of the actual validity of digital signatures, the correctness of the flows applicable to sensitive data. Also in this area there is a lack of training, due to a lack of models and guidelines, which jeopardizes the possibility of carrying out research projects conducted with innovative, efficient, dematerialized methods that optimize the sources of information.

In the third session entitled "New Frontiers in Clinical Trials", speakers from the world of production, communication and research discussed what could be the challenges of the future. They reported their experience in the fields of artificial intelligence projects, telemedicine, "industry 4.0", fundraising at international level, where innovation and digitization are the keys to access, they discussed what is provided to researchers abroad, the different professional consideration in particular.

Outcome: *the testimonies of the speakers suggest that we have all the tools to represent a model of innovation, to be able to support and propose the "P medicine", Personalized, Predictive, Preventive and Participatory, but we need to verify and validate the methods proposed, building interdisciplinary networks and preparing a path of support with institutions, called to ensure the validity of this work, perhaps proposing it as a uniform model to be pursued.*

In the fourth session entitled "**The Active Role of Patients**", the speakers from the world of Institutions, pharmaceutical companies, research organizations and patient associations discussed the issue of the real active involvement of patients in the processes of conception, evaluation and execution of clinical trials. They discussed the experience gained, with patients as indispensable interlocutors, both from the point of view of inclusion in the search for the satisfaction of needs not considered or found, and in the verification of what has been implemented so far. There was also the testimony of an association of pediatric patients, an expression of the attention of the world of clinical research not only limited to the adult population.

Outcome: *Patient associations now represent recognized partners in the world of clinical research and actively contribute to the work through training and dissemination initiatives. The theme of informed consent has been considered fundamental and the digitization of the same an opportunity to be seized. The training of "expert patients" in clinical research represents the new frontier, useful to have the contribution of those directly interested in the quality of clinical trials, to ensure that they meet the real needs of patients and not only theoretical models. Therefore, the collaboration between researchers, pharmaceutical companies, CROs, patient associations and institutions can create the necessary synergy to qualify Italian research at the high levels to which it can aspire in the international context*.

In summary, the points that emerged during the AICRO event should be immediately "taken care of":

- The recognition of professional figures related to independent research
- Regulatory Simplification
- Need to provide appropriate technological tools and methodological guidelines about digitization
- Development of a public-private partnership model (ppp), also able to enhance networking experiences and integration of research infrastructures
- Development of a model of public and patient involvement (ppi), capable of directing investment in research and health to meet needs.
- Fiscal incentives (also in terms of labor costs) to companies that invest in research.