AICRO

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CLINICAL RESEARCH BETWEEN BUSINESS AND EDUCATION

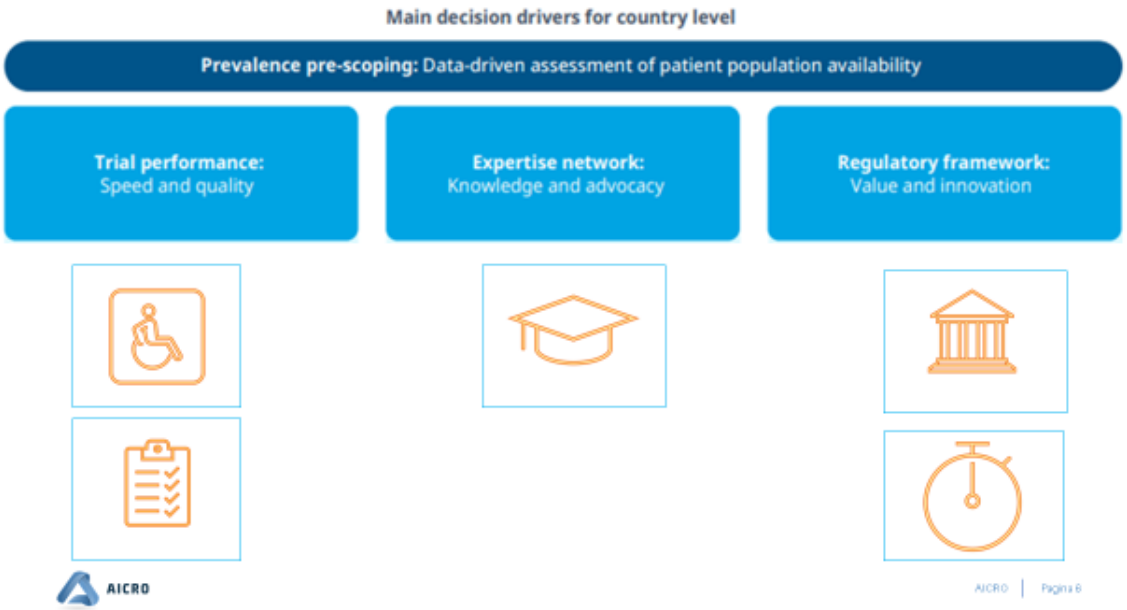
What it takes to succeed

Menti a Contatto - AICRO 2022 EVENT

Summary and Disclosure Document

On 2 December 2022, 'Menti a contatto', the annual appointment of AICRO (Italian Association of Contract Research Organisations) was held in Milan. Large attendance in attendance and remotely for a day dedicated to the world of Clinical Research: its value, the needs of those who want to make a business out of it, the opportunities and perspectives in the workplace.
The intention of this format is to bring together all stakeholders involved in clinical development, albeit in different areas and sectors, and to stimulate reasoning, collect experiences and consensus from different points of view.
Last year we 'connected' the topics of digitisation and modernisation with the new frontiers in Clinical Trials and with patients and their active role in research.
This year we went even further: we took for granted the need for synergy between researchers, promoters, CROs, patient associations and institutions, in order to qualify Italian research to the high levels to which it can also aspire in the international context, and we addressed the issue of research in Italy from an equally important point of view: that of economic feasibility, funding, training, skills and the possibility of attracting investment, and the regulatory framework.

Research needs investment in order to function, according to what was discussed and shared by the different actors, who fuelled the 'minds in touch' day.
We collected testimonies from those involved in sponsored research, independent research, the pharmaceutical world, the medical device world, the start-up world and those who have to manage public funding.
"Menti a contatto" this year delved into the relationship between clinical research - industry and education in order to identify which strategies to implement for the success of entrepreneurial initiatives and ultimately of the entire research chain. It was a multi-voice debate that really offered a lot of food for thought. The question that everyone shared, a more focused declination of the general theme, was:
In R&D, what does it take to be successful in Italy?
To steal the words of one of the speakers: "an enabling health context".
How better to define it? AICRO President Fabrizio Forini announced at the opening: a system of skills and experience must be established that enhances and supports research and experimentation initiatives. There must be a regulatory framework geared towards increasing the added value of research and open to innovation. It must be possible to execute quickly and in accordance with the highest quality standards.

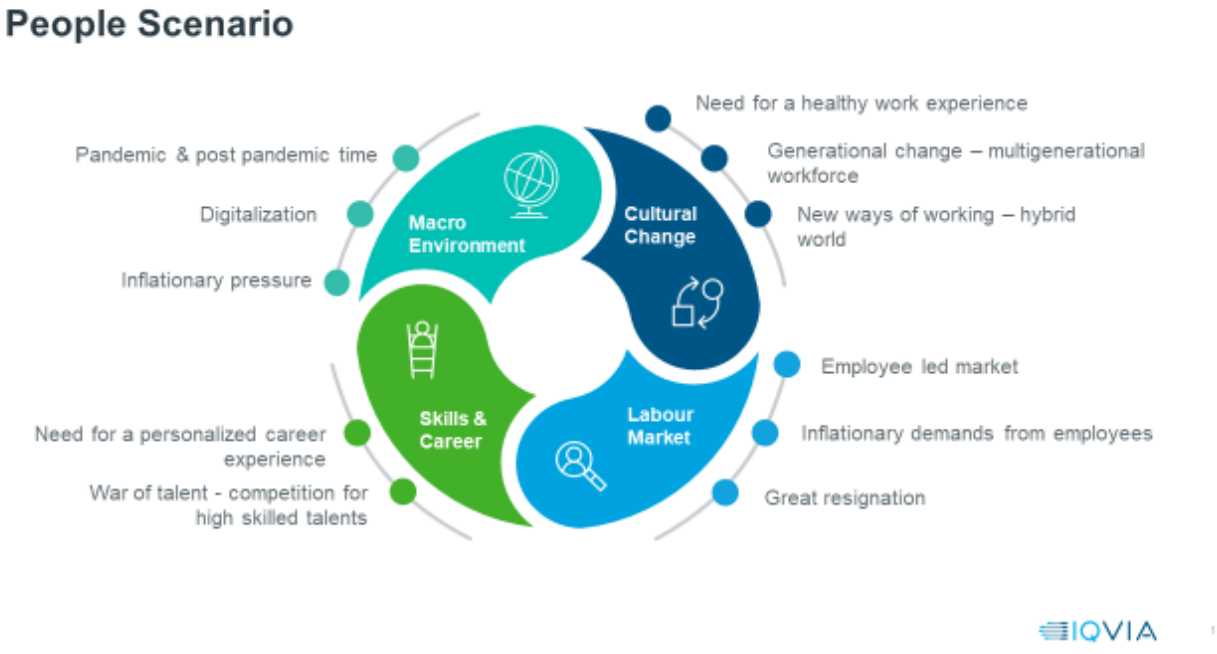


The two sessions in which the day took place ('Business and clinical research start-ups in Italy: the opportunities and challenges' and 'Rethinking clinical trials: evolution and formation of roles in clinical research') allowed for a timely and, if you like, 'strategic' focus on all the implications that an 'enabling healthcare context' would have in different areas, starting with health, and then translating into opportunities for technological development, economic opportunities and employment of human resources.
In Italy, more awareness is also needed among institutions, and an interaction between different ministries is desirable, not only the Ministry of Health, but also Economic Development, Education and University, with an overview of the various components and the possible contribution of an effective synergy of interventions.
What emerged in unison from both sessions was that we are currently at a disadvantage compared to the major European countries. We need, for example, a guideline on Digital Health, as has already been implemented in the USA, Germany and soon in France. Restrictions on the use of retrospectively collected data need to be simplified; in this area too, for example, the French model has best interpreted the dictates of the GDPR. In general, shorter timeframes are needed for handling bureaucratic processes.
Finally, we need new competent human resources and incentives and tools for those who want to invest in product development.

An efficient research environment: in the face of so much enthusiasm and 'vision' on the part of researchers and companies, we see inefficiencies in approval processes, long evaluation times and lack of interest on the part of administrative offices. Inefficiency can lead to the risk of project failure, which is particularly critical for a start-up. This risk can lead investors to choose other countries for research projects, excluding ours. The recent introduction of European Regulation 536 should bring greater uniformity at least in the activation and conduct of interventional clinical trials, as well as a reduction in approval times; however, we have recently seen how some decisions taken centrally, without adequate consultation with all stakeholders, can be more of an obstacle than a stimulus to contemporary clinical research.

An incentive financial environment.
We are witnessing an increased general interest in clinical research on the part of private investors, be they manufacturers or investment funds. However, there is little capacity to attract such investments in Italy. One of the greatest shortcomings is the lack of awareness of the economic value of research and the unwillingness (especially on the part of institutions) to constructively confront more modern and advanced dynamics.
Public investment and tax incentives are relatively low and there are no truly representative players in independent research, while there are multiple institutional stakeholders with often unclear divided competences.
Here, too, there is a need to encourage more discussion and the ability to channel investment where there is mature interest and expertise. Quick decision-making and fast disbursement of funding are further necessities, especially for the most innovative companies (start-ups).

A competent clinical environment is needed: extensive training for healthcare professionals, for patients and for all roles involved in research.
The skills available for health professionals and research associates are not always adequate to the needs. Despite the academic training offer available for young people interested in research, there is a very pronounced gap with the needs of the working world. Furthermore, especially for the medical profession and for research coordinators at experimental centres, there is no comprehensive training offer in modern clinical research. All stakeholders want to make an effort to raise the level of awareness of the value of clinical research even among those who run the largest trial centres. Actors who, at present, do not seem to be adequately involved. Without this awareness and commitment to creating a favourable and competitive environment, there can be no real development and progress capable of promoting and attracting clinical trials to Italian centres.
Training offers, Master's degrees, Academies must seriously confront the real opportunities this sector offers and the professional skills it needs.



CONCLUSIONS:
Clinical research cannot be reduced to a contract between a promoter and performers. We can and must aim for an integrated research system, take advantage of technology, international regulatory developments, seize opportunities in the European context, and develop expertise.
Investors require predictable timeframes and strict conditions, which are difficult to sustain in an inefficient and non-enabling environment. Entrepreneurial competence that is collaborative and proactive, especially in the health sector is a necessary development for all players.

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Perhaps 'Menti a contatto' comes at the right time, precisely because it takes into account the important changes taking place in our NHS and the health system in general and offers stimulus to all stakeholders, including institutional bodies.
AICRO will take this common feeling forward and act as an experienced and knowledgeable stakeholder, ready to provide input and expertise.

By the Scientific Director
Milan, 8 February 2023

SPEAKERS
Maurizio Belfiglio, Director of the Independent Research Office - AIFA
Elena Bresciani, Referee of the Master in Preclinical and Clinical Drug Research and Development Department of Medicine and Surgery - University of Milan Bicocca
Celeste Cagnazzo, President - GIDM Gruppo Italiano Data Manager
Marco Casucci, Sr Director Regulatory Affairs - Precision for Medicine
Gennaro Daniele, Director UOC Phase 1 - Fondazione Policlinico Agostino Gemelli IRCCS and R&D Director - Clinical Trial Center S.p.A.
Fabrizio Forini, President AICRO - IQVIA RDS Italy
Stefano Fili, Research and Services Manager, Leyton Study Centre Manager
Fulvio Fortini, Managing Director - Healthware International
Michela Franchini, Researcher in Epidemiology, Participatory Research and Movement Sciences Human, Institute of Clinical Physiology - CNR Pisa
Fernanda Gellona, Director General - Confindustria Medical Devices
Fabio Giordano, CEO - CD Pharma Group
Stefano Gregoriani, Sr. Director Clinical Monitoring - Caidya
Gualberto Gussoni, Scientific Coordinator - FADOI Study Centre
Elena Manna, Manager Clinical Operations - IQVIA Italy
Eleonora Maretti, Ph.D, CEO - PerFormS S.r.l.
Antonino Musolino, President of the Italian Oncology Clinical Research Group (GOIRC)
Pierluigi Navarra, Full Professor of Pharmacology and Director of the Chair of Pharmacology, Department of Safety and Bioethics, Faculty of Medicine - Catholic University of the Sacred Heart - Rome Branch
Elena Ottavianelli, Scientific Director AICRO/CTS Training School Mycroscope - Fullcro
Valentina Pigatto, HR & Talent Acquisition Manager - JSB Solutions
Giuseppe Recchia, Co-founder & CEO - daVi DigitalMedicine S.r.l.
Denise Ronchi, HR Business Partner - IQVIA RDS Italy
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Elisa Tomasin, Clinical Operation Manager - JSB Solutions
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