pharmadvances
Volume **4**, special issue, **2022: 5-8**

INTRODUCTION

G. Racagni[1,2], N. Martini[3], M. Zibellini[4]

[1] Italian Society of Pharmacology (SIF), Milan, Italy
[2] University of Milan, Milan, Italy
[3] Research and Health Foundation (ReS), Rome, Italy
[4] Technical Scientific Direction at Farmindustria, Rome, Italy

In the development of innovative drugs, new technologies and healthcare processes in modern medicine, the need and importance of integrating pharmacological research (PIL) with the pharmaceutical industry's R&D processes is unanimously recognised, through partnership procedures, the strategic value of which was also clearly confirmed during the pandemic period.
Efficient collaboration between public and private research organisations, start-ups, science parks, non-profit organisations and businesses can spread new knowledge, skills and good practices, fostering a shared culture on the new frontiers of science and technology.
Partnership without which it would be impossible to excel at all stages of the research process, from clinical trials to access to treatment for patients. And that makes the pharmaceutical industry one of the most advanced examples of Open Innovation.
The healthcare crisis has made clear the need to further strengthen public-private collaboration to accelerate the innovation processes already under way and to improve the health and life expectancy of citizens. And to attract new resources and talent for the economic and social development of the country.
That's why we need tools and clear rules to encourage basic research, preclinical and clinical studies, registration and protection of patents, technology transfer and digital information. This is the only way to make the Italian innovation ecosystem stronger. For the benefit of today's and tomorrow's patients.
However, the partnership between public and private structures often risks becoming a rhetorical evocation or remaining tied to an institutional conception of conflicts of interest and conflicts between science and the market.
This SIF publication, overcoming all prejudices, addresses the key points and most challenging issues of new drug development and healthcare

edra

strategies, reporting the results and concrete contributions of an active partnership between the pharmacological community (SIF) and the R&D processes of the pharmaceutical industry (Farmindustria).
The document stems from the observations that emerged during the regular SIF-Farmindustria table meetings held during 2020-2021, as well as from the 40th National Congress of the Italian Society of Pharmacology (March 9-13, 2021).
In particular, the SIF-Farmindustria issue is structured in 6 parts and contributions:

1. the new research methods;
2. data quality;
3. the patient and their treatment needs;
4. breakthrough innovation and PDTAs;
5. digital innovation in medicine;
6. the role of science communication.

The collection provides an overview of the most relevant and significant issues for the changes that pharmacological research and the pharmaceutical industry are facing, with particular attention given to their innovative nature and sustainability for the health system as a whole.
Each contribution is structured in such a way as to outline the current context from which proposals and areas for future development can be made. These form the *core* of each individual contribution and provide extremely important points for discussion and reflection for all those involved in various ways in the world of drug research and new treatment processes.
It starts with new clinical research methods, which are driving the increase in research pipelines, not only quantitatively, but especially qualitatively. In fact, they are more focused on identifying "*first in class*" therapies, biotechnology products, advanced and digital therapies. In order to achieve these objectives, it is essential to develop new study designs and to define paths that can accelerate access to drugs while reducing development costs, and to adopt a regulatory framework capable of regulating and making the new methods of research and access to drugs more efficient.
Subsequently, the role and quality of scientific data in conducting research at all stages of a drug's life is addressed: from preclinical to the study of its use in current clinical practice. In fact, the data is the real fuel for research and, therefore, it is of the utmost importance to have reliable sources, adequate infrastructures and the skills to manage and analyse them. This transition is becoming more and more imminent, especially considering the challenge posed by the *big data* that we generate on a daily basis on our state of health and which represent the real-world scope of wide-ranging research.
A central part of the collection is devoted to the theme of "innovation", approached from different angles: as incremental patient-centred inno-

vation, radical (*breakthrough*) innovation, and, finally, as innovation related to digital medicine.
Incremental innovation, *i.e.* innovation aimed at developing an optimised version of a product already on the market, should increasingly be patient-centred, given the social changes we are experiencing. In this context, research should be aimed at identifying new strategies to promote appropriateness, foster adherence, simplify treatment, and reduce barriers to patient access to treatment. This type of innovation, however, needs greater recognition within the health system; consequently, it becomes essential to devise strategies capable of quantifying and defining it adequately, according to precise algorithms.
On the other hand, when the innovation helps us to treat a never-before treated disease or profoundly modifies its clinical history, it can be defined as radical (*breakthrough*), *e.g.* CAR-T (Chimeric Antigen Receptor T cell therapies) or the agnostic therapies underlying mutational oncology. Thanks to the speed and quality of research and development processes achieved in recent years, this type of innovation is becoming more and more present and it is therefore strategic to study its organisational implications, as well as its technical, regulatory and economic requirements. In fact, only by combining this innovation with new organisational models will it be possible to allow rapid and equitable access to the most innovative treatments within the framework of the costs of care (PDTA). These new models can benefit from forms of public-private partnership, from the ability to assess the whole process and not just a single variable, and from the tools made available by digital medicine and artificial intelligence applied to health.
A separate contribution in the collection is devoted to digital medicine and its revolution in healthcare. In fact, digital therapies, whose efficacy must be evidence-based like other therapies, can be used independently or in combination with drugs, in order to optimise patient treatment and to enable the achievement of desired health outcomes. However, given the paradigm shift associated with these new therapies, it is essential to design an appropriate regulatory pathway that focuses on their efficacy, the integrity and quality of the data collected, and their impact on the organisational model. Only in this way will it be possible to properly value these therapies, taking into account the overall benefits they bring to the process as a whole, as well as the individual, health, social and professional consequences.
The collection closes with a contribution on the important aspect of scientific communication, which, as the pandemic has taught us, represents a crucial point for consolidating public trust in the pharmaceutical sector, as well as for renewing the alliance between health *stakeholders* for the benefit of patients. While it is important to ensure transparent and complete publication of data, whether positive or negative, it is also essential to ensure that scientific communication is appropriate for the target audience in terms of content and language. This is especially true

when addressing the public and patients, who need as clear and understandable communication as possible.
By following the common thread linking the collection's various contributions, it is possible to understand where drug research is heading and where drug companies have demonstrated, and continue to demonstrate every day, their ability to innovate and network by combining science and technology, human skills and artificial intelligence, and public and private excellence.
In order to understand the complex, multidisciplinary and global processes of Life Sciences, a structural confrontation between public and private stakeholders is needed to network all competences. The word 'partnership' is not merely a slogan, it is a strategic competitive factor, indispensable when it comes to finding innovative and shared solutions to the country's real needs.
For the pharmaceutical sector, increasing synergy between the public and private sectors means increasing research, generating added value through economic, social and environmental sustainability, improving patients' access to treatment, increasing employment and expertise, and investing even more in the green transition.
Therefore, it is possible to consider this collection as a possible map for the future (not so far away, considering the speed at which innovation processes currently travel) that may be useful to the world of pharmacological research and to the world of R&D investments by pharmaceutical companies.