INNOVATIONS IN CLINICAL TRIALS FOR NEW TECHNOLOGIES IN THE ERA OF COVID-19

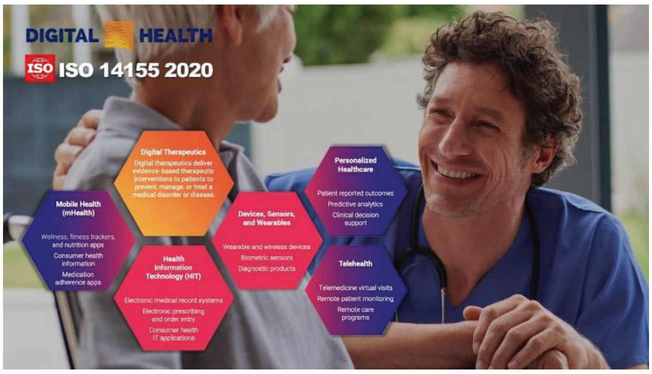
by Monica Tocchi, MD, PhD

Explosion in digital health

The Covid emergency has opened the floodgates to a digital revolution in all sectors of healthcare and wellness. An acceleration that now needs to be managed, governed, taking full advantage of the opportunities and minimizing the 'side effects'. 'Digital health' encompasses the monitoring of one's own health through the tools - such as the applications, the supports that detect patient data - that are more accessible today than ever before. Demand for digital tools has been boosted by Covid, that has imposed new models of behavior and distancing of patients from healthcare facilities. It is no coincidence that the latter are now increasingly specialized in 'remote', digital medicine.

New opportunities and challenges

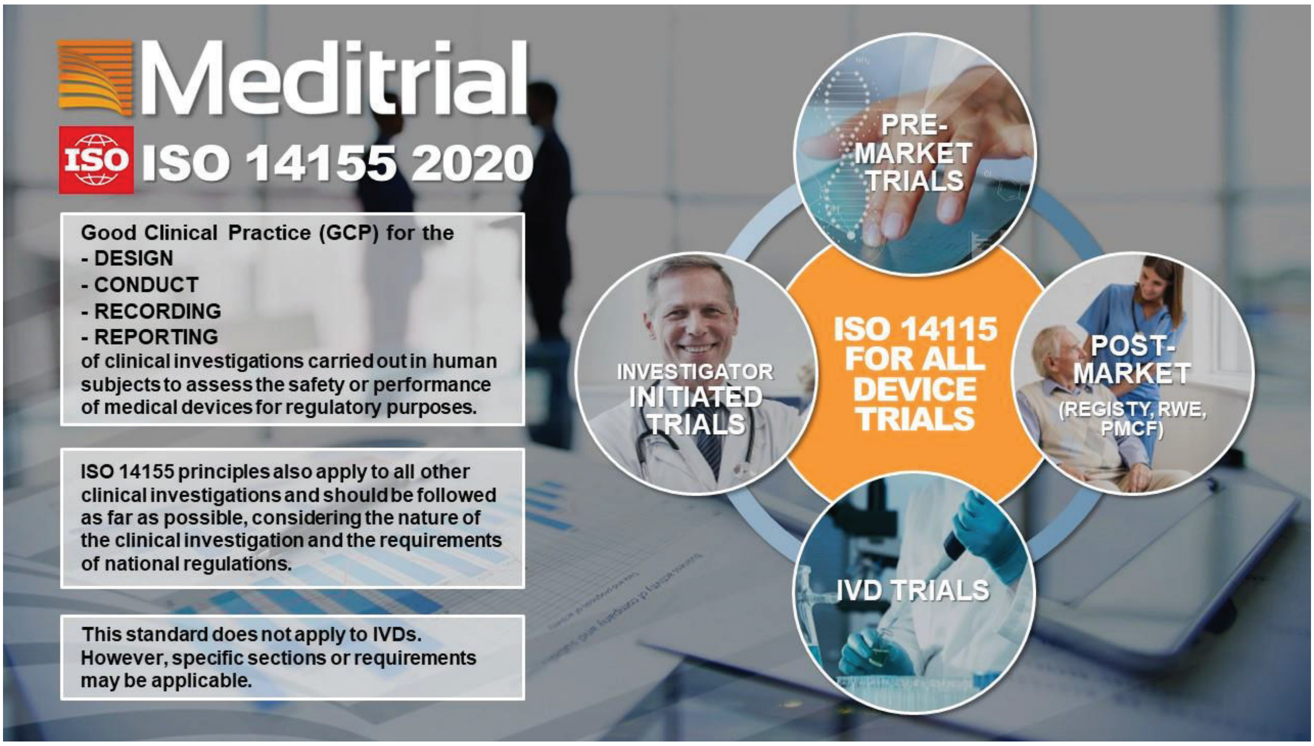
The digital revolution underway and driven by Covid confronts us with substantially new opportunities and challenges. A mass of health-related and behavioral data that must be validated on the basis of clear and certified parameters. Just think that even the simple application that we download to our phone, obviously linked to the monitoring of specific health parameters, is in all respects a 'medical device'. Clearly this trend also exposes us to potentially misleading and far from scientific data. This drives the need for new regulation to provide a framework for quality and validation, at the same time avoiding undue obstacles to innovation.



Healthcare software excalation

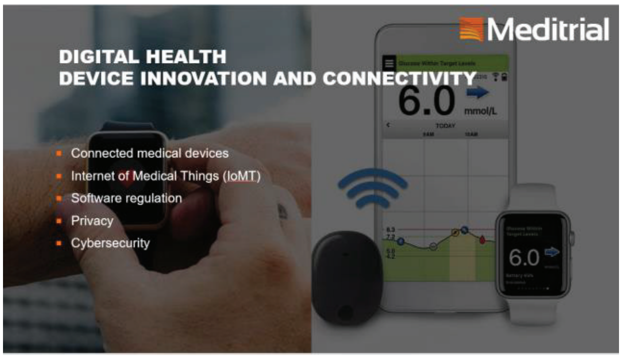
Rapid expansion of healthcare IT and modernization of healthcare systems will drive the software segment to unprecedented heights.

A growing demand for digital health software such as electronic health records (EHRs), fitness and medical apps, and healthcare analytics will drive the segment growth. The rising number of COVID-19 cases have created a need for software to record and track the COVID cases, thereby, propelling the demand for EHRs. Furthermore, due to shutdown of gyms and recreation clubs, there will be a growing demand for fitness apps. Also, growing geriatric population and rising chronic diseases will create a demand for medical apps. These factors will drive the digital health industry growth.



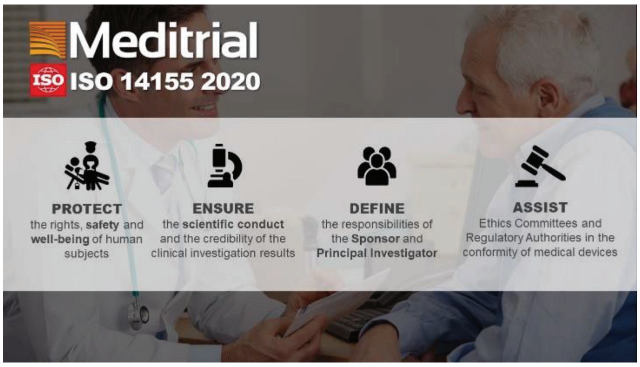
Connected Devices

A growing incidence of chronic diseases due to unhealthy lifestyle will increase the patient pool. This will result in an increased demand for hardware such as glucometers, and BP monitors. Growing geriatric population across the world will have a positive impact on the product demand in the market. These factors will drive the segment growth and boost the industry demand for devices and integrated solutions.



Innovation in clinical trials and value-based outcomes

The new regulation for medical device clinical trials - ISO 14155 – represents the common framework for conducting clinical trials in the COVID-19 era and beyond. It contains specific guidelines for carrying out clinical studies on medical devices and defines the role, in this context, of sponsors, researchers, ethics committees and authorities.



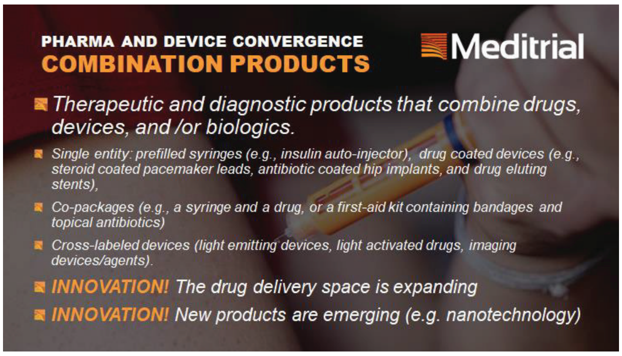
This new standard, ISO 14155:2020, introduces key innovations to run better trials, not only for market approval of medical devices and digital health technologies, but also to collect more evidence when devices are placed on the market.
Knowing this standard is fundamental today, when we consider the increasing demand of value-based evidence for digital devices, connected devices and digital therapeutics, and the new modalities for virtual trials and real-world evidence.

Global Harmonization

The 2020 revision of ISO 14155 is a truly transformative regulation that will allow sponsors to run trials anywhere in the world.

By following this standard, companies and hospitals in any geography will be able to generate data that will be accepted by the US FDA and also by European and Asian regulatory authorities. In fact, the standard has been aligned with the new European Medical Device Regulation, US FDA regulations and global requirements, enabling seamless compliance and removing barriers to scientific progress.

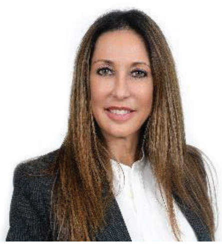
This standard is also aligned with pharma requirements and therefore, it is helpful for trials of combination products, connected devices and digital health.



New horizons for the healthcare system and society

A major implication of the healthcare system transformation, is the need to inform and train healthcare professionals who deal with biotechnologies and digital health data, as well as patients and regulators. From nurses to professionals in the clinical research sector, from those who offer 'social' services - but in an increasingly innovative way - to doctors. Once again, the basis is the knowledge of new technologies, of the rules applied, as well as that set of skills - linguistic, economic, managerial - which are the basis of the competitiveness of each figure.

In a context, such as Covid's, where needs emerged that often found partial, incomplete answers, not based on clear scientific criteria, the experts have to tidy up, qualify, invest in professionalism looking at the excellence of each single step. Tools, standards, specific qualities of the professional. In this sense, the virus is a test bed and an opportunity to reach tools that only yesterday seemed blocked, stranded by the absence of a real need which today has emerged in all its evidence. In this phase of global crisis that has affected all of us, the entire scientific and academic community needs to devote programs and resources to supporting the healthcare community, the patients and society, creating dedicated training programs, in every country all over the world.



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