

Digital Biomarkers: why Precision Medicine need them

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Abstract. "The advent of digital tools presents the opportunity to revolutionize the data capture methods – specifically, the ability to collect more specific, relevant data points or digital biomarkers".

According to Rock Health's report, digital biomarkers are "consumer-generated physiological and behavioral measures collected through connected digital tools" which "represent an opportunity to capture clinically meaningful, objective data in a cost-effective manner."

Research can tremendously benefit from longitudinal data capture throughout a subject's daily life, gaining accuracy through disease-specific algorithms designed to process subject data quantify the severity and progression of symptoms or alerting about signal warning suggesting intervention.

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Opinion

Precision Medicine has rapidly become the horizon to look at, and this is a trend which is destined to grow. However, some limitations and open problems remain to be solved.

For example, how effective will be data integration at a global scale? How to harmonize geo-differentiated information and manage ethnic balance? What is the status of consensus over protocols for digital repositories involving transferability of structured and non-structured records? These are examples of "missing links", i.e. gaps that need to be addressed to speed up the optimization of decision making processes governing Precision Medicine. The achievement of actionable steps implies that synergies must be enabled at various levels.

Consider one of the priorities: establishing markers of diseases and associated comorbidities. This no doubt remains an open frontier. What we have now available to diagnose and cure is clearly insufficient, especially with several complex diseases, and despite many clinical progresses, technological advances, and overall changes affecting individuals and societies that have gradually assigned a central role to personalized decisions with regard to prevention, cure and care.

Benefits are expected from the influence of factors with marginal or none role in the past. Interestingly, not only patients but healthy individuals too are targets of next generation studies. Wellbeing, healthy ageing, stress balance have become popular terms. And many interests, including economic ones, are centered on risk profiles derived from personal histories, electronic clinical records, physiological measurements, genetic information, socio-economic determinants, environmental and social influences, nutrition aspects and more.

An effective interoperability between many resources outsourcing all such multi-dimensional information is crucial, and a way to address this need is to provide measures of synthesis defined through Digital Biomarkers. They are defined as indicators of health status obtained from medical devices, mobile technologies, software tools, wearables and apps measuring physio-pathological and behavioral parameters in both active (at the gym) and passive (during sleep) conditions, day and night, everywhere.

This definition can in my view be expanded, considering Digital Biomarkers as extensions of molecular and clinical markers obtained by connecting other layers of complementary information relevant to health status. Not by chance the sector of digital health includes among its categories digital therapeutics, one destined to be highly dynamic in the near future. Therefore, the model which is likely to be sustainable may be based on integrated cross-linked digital records available to doctors for timely and effective patients management.

Ultimately, and most importantly, by looking at digitally organized, standardized and curated data, the quality of care will improve. This would be consequence of a process of data democratization, an hybrid generated by the fusion of web social influences and data liquidity. An assumption is that a recognized new role in this process involves patients, more actively role controlling factors falling outside the doctor's sphere, say life-style, technology and socials. Social implications, in particular, are key to determine the role of Digital Biomarkers dynamically. This is a natural consequence of the fact that the complex multifaceted underlying data generative process at place is subject to variation at both individual and small-to-large community scales.

Novel uses of social media are de facto inspiring a 360-degree re-assessment of health and disease, in terms of interactions (care and cure), perception of conditions (self-quantified), remote delivery or monitoring (telemedicine), and community medicine models. Collectively, these advances will open up limitless opportunities that may become concrete benefits once cleared from biases and confounders, and instead elucidated by factors significantly tested to be determinants of lifestyle modifications. Let us think for a moment, and objectively: how many years have we listened to possible health risks from multiple forms of addiction, say cellular phones, TV, web, emails, till occasional use of alcohol and drugs? And, what do we really know from the consensus reached so far? Not much, as no consensus is presently there.

Therefore, a sort of new health chapter will be written by Digital Biomarkers, one with a title including the word “epigenetic hallmarks”, and with a word that should not be missing, “people”.

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