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A Short Note on Biorepositories and Biomarker Development

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Description

Biomarker development has become an essential technique in the development of personalized medicine drugs. The need for biomarker development, which is a Companion Diagnostic medical device (CDx) that allows treating the right patient at the right time with the right drug or drug combination at the right dose, is being driven by rising health-care costs for biologics therapeutics combined with individualized, personalized medicine. Early biomarker development might be enhanced by using biorepositories or biobanks of human-derived specimens that represent the disease of concern.

Legally permitted biorepositories or biobanks may therefore serve as a versatile "tool" for determining performance attributes and/or analytical/clinical validity of *in vitro* diagnostic medical devices in the context of medication usage prior to entering the clinical phase. Biobank authorization for research and commercial use stems from adherence to the Declaration of Helsinki, and is based on principle of national and international legislation, statutory requirements, and informed consent provided by donors, though informed consent may be waived in some circumstances.

Despite the fact that the new Regulation on *in vitro* Diagnostic Medical Devices (IVDR) went into effect on May 26, 2017, Europe is now facing a 5-year “grace period” in terms of transitioning rules for CDx biomarker research. Even in the absence of contemporaneously sourced clinical trials specimens, changing regulatory conditions and the availability of various biorepositories, combined with new European unequivocal provisions for CDx biomarker development and conformity assessment procedures for approval (CE-marking), may allow for the development of biomarker performance characteristics and/or analytical/clinical validity. This article shows the problem connected with the CDx biomarker in the usage of biorepositories and offers some light on regulatory challenges with respect to anticipated changes with the IVDR.

Personalized medicine is the fastest-growing field i n medical research, with the goal of solving unmet medical needs by moving away from the traditional therapeutic strategy of using anti-cancer drugs in tumour therapy and toward individualized, precision medicine. Understanding the aetiology of cancer and unravelling molecular pathways has led to the development of drugs that target not only oncologic but also autoimmune and inflammatory diseases, as well as immuno-oncology disorders. A biomarker, according to the FDA and the Biomarker Definition Working Group, is “an objectively measured and assessed feature that is used as an indication of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention.” The particular biomarker development targeting protein, DNA, or RNA checked for in the specific context of medication usage has transformed personalized medicine dramatically. Companion Diagnostics (CDx), which is *in vitro* medical diagnostic instruments) has revolutionized precision medicine substantially. The high cost of monoclonal antibody therapy has contributed considerably to the high healthcare burden, but the use of biomarkers might enhance health care while also lowering expenses. Routinely evaluating individuals with colon cancer for mutations in the K-RAS oncogene might save at least $600 million each year, according to the American Society of Clinical Oncology. This may require taking into consideration predictive as well as pharmacodynamics biomarkers for patient selection or pharmacodynamics effects of a medication, among other factors. Unfortunately, health-care systems have not yet fully cleared the way for reimbursement of innovative biomarker-based medicinal laboratory tests for personalized treatment, which may or may not provide a focuses for biomarker research.

Conclusion

To summaries, legally, locally authorized biobanks or biorepositories may be a useful tool in the early development of performance characteristics and/or analytical/clinical validation of CDx, while the new Regulation on *in vitro* diagnostic medical devices has finally filled in the regulatory gaps on companion diagnostics biomarker development in the specific context of drug development.