Publication with contribution of BBMRI

"Pre-analytical processes in medical diagnostics: New regulatory requirements and standards"

Georges Dagher, Karl Friedrich Becker, Serena Bonin, Carole Foy, Stefania Gelmini, Mikael Kubista, Penelope Kungl, Uwe Oelmueller, Helen Parkes, Pamela Pinzani, Peter Riegman, Ulrike Schröder, Cornelia Stumptner, Paola Turano, Robert Sjöback, Andrea Wutte, Kurt Zatloukal

In the context of the H2020 project SPIDIA4P this paper on the relevance of standards on sample pre-analytics particularly in the context of the new in-vitro diagnostic regulation (IVDR) was published. Authors from BBMRI.at partner Med Uni Graz and BBMRI-ERIC contributed to it.

The paper provides

- an overview of the European MDR and IVDR
- the relevance of pre-analytical parameters for product verification and validation
- An overview of new standards on sample pre-analytics
- A discussion of challenges in complying with the IVDR

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New BIOTECHNOLOGY

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ARTICLE INFO

ABSTRACT

Introduction

Bundesministerium Bildung, Wissenschaft und Forschung

Funded by
GZ 10.470/0016-II/3/2013 (2013-2018)
BMBWF-10.470/0010-V/3c/2018 (2018-2023)