

**QUALITY POLICY
MTZ CLINICAL RESEARCH
QUALITY MANAGEMENT SYSTEM ACCORDING TO EN ISO 9001:2015**

**Our company's motto is "Quality is a member of our team"
The company's main values are: quality, cooperation and honesty**

The most important objective of MTZ Clinical Research is reliable and comprehensive conducting of clinical trials, based on legal regulations and ethical standards, ensuring the safety of Participants in accordance with the context and strategic direction of the organization. By acting as described, the company creates significant values for the company's shareholders and ensures the integration of quality management system requirements with the organization's business processes.

We obtain the QUALITY and VALUE of the Company required and declared to Sponsors by:

1. Monitoring and proceeding in accordance with the current legal acts regarding the requirements of Polish, European and North American registration authorities, allowing to ensure high quality of clinical trials and safety of volunteers/patients participating in clinical trials, with full protection of their dignity and respect for rights, as well as guaranteeing confidentiality.
2. Monitoring of legal acts and regulations referring directly to fields related to the activities of MTZ Clinical Research Sp. z o.o. supporting clinical trials conduct.
3. Proceedings guaranteeing conducting clinical trials at MTZ Clinical Research in accordance with applicable standards of Good Clinical Practice ICH GCP using a process approach and risk-based thinking.
4. Ensuring the highest quality of services provided by the Laboratory of Medical Analysis MTZ Clinical Research Sp. z o.o. in the field of laboratory diagnostics.
5. Regulating activities with internal Standard Operating Procedures that guarantee a high degree of clinical trial standardization and the Participants' safety, to which we attach great importance.
6. Preparation of documentation in accordance with the requirements of Polish, European and North American registration authorities.
7. Employment properly educated and qualified people and continuous improvement of their knowledge and skills through regular training (including confidentiality training).
8. Providing employees with training in regulations regarding the conduct of clinical trials.
9. Providing employees with regular training in Good Clinical Practice (GCP) and Standard Operating Procedures (SOP) as well as emergency procedures (emergency situations).
10. Building the best relationships between employees, providing them with appropriate infrastructure and work environment.
11. Taking responsibility of each employee for the quality of their work.
12. Guaranteeing continuous access to current legal regulations and training in conducting clinical trials through employee membership in the Polish Association for Good Clinical Practice (GCPpl).
13. Conducting internal system audits on projects and suppliers in accordance with the Audit Plan.
14. Submission to Sponsor audits, regulatory inspections and implementation of post-audit recommendations.
15. Supervising the correct conduct of the research project in terms of quality by the Quality Management Department to ensure that the quality management system achieves the intended results.
16. The Top Management involvement and support people who have influence on the effectiveness of the quality management system and its continuous improvement as well as supporting appropriate management roles to demonstrate their leadership in their areas of responsibility.
17. Ensuring the security of information assets processed at MTZ by implementing organizational, technical and physical controls in accordance with the implemented Information Security Management Rules developed on the basis of the requirements of the EN ISO / IEC 27001: 2017 standard.

Top Management puts emphasis on increasing satisfaction of Sponsors commissioning MTZ Clinical Research to conduct a clinical trial by taking into account specific risks and opportunities that may affect the compliance of the provided service.

Approved by: August 27, 2020

Teresa Brodniewicz-Proba, PhD
President
Scientific and Business Development Director