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Clinical Trials Statement

Quality for life

Ottobock stands for high quality and technologically outstanding products and services. With this commitment to quality, Ottobock is well aware of accepting a high level of responsibility in its research activities. The Clinical Trials Statement is complementary to the Company's Standard Operating Procedures and the subordinated laws, regulations and guidelines applicable to clinical trials. Ottobock is committed to conduct all clinical trials in an ethical manner and to follow all international guidelines as well as local laws and regulations in the conduct of its clinical research programs. All Ottobock clinical studies are conducted in full conformance with the principles of the Declaration of Helsinki and with the laws and regulations of the country in which the research is conducted to provide the greatest protection to the individual. Besides, the principles outlined in the "Guideline for Good Clinical Practice" ICH Tripartite Guideline are considered to be the minimum standard for any of Ottobock's clinical trials. Ottobock does not outsource clinical studies. However, in the unlikely event that Ottobock does, all guidelines and principles apply equally, and the outsourced trials shall be regularly monitored.

Trial Procedures

1. Responsibilities and Study Evaluation Board

Ottobock assigns clear responsibility for ethical conduct to our Clinical Lead and the Clinical Project Manager. An independent ethics committee, the Study Evaluation Board (SEB) is responsible for the supervision of all clinical trials. The SEB consists at least of a Vice President of Global Clinical Research Services, a Head of Strategic Marketing Unit, and an area expert from Clinical Research Services. The SEB is usually accompanied by the CTO and the CSO. The SEB enforces ethical conduct and is entitled to approve, modify or stop trials anytime.

2. Employee awareness and trainings

Ottobock commits to the highest quality and standards for clinical trials. This includes training and awareness programs for all clinical trial employees. Every new employee receives an individualized training plan to support his journey at Ottobock. This includes, for example, extensive training on Ottobock's products, clinical evaluation, standard operating procedures, ISO 14155 and medical product laws. Besides, Ottobock strive to create awareness for responsibility in trials and the importance of ethical conduct through different programs.

3. Trial application procedures

Ottobock has standardized, pre-defined procedures before the start of a study. The idea for a clinical study must be submitted by means of an application with a pre-evaluation form to the SEB. Part of the review by the SEB includes a risk and impact assessment before any trial begins. Ottobock's risk management team conducts a product-related risk assessment,

while the Clinical Project Manager complements the study-related risks. Only after carefully considering all the risks and impacts will the SEB approve or deny the start of a trial.

4. Participant solicitation process

In the case of a successful approval, our standardized process to solicit participant's starts. An important aspect of the Declaration of Helsinki is informed consent, which is an integral part of Ottobock's process. Each participant has to give their free, prior and informed consent. The signed and dated informed consent forms must be obtained for documentation from each subject at the point of enrollment or before any clinical investigation related procedures are undertaken.

5. Monitoring and reporting

Ongoing trials are subject to extensive regular monitoring. Ottobock's Standard Operating Procedures for monitoring provide guidance to all clinical trials. A study needs to be staffed with qualified monitors, either from a clinical research organization, consultants or the Clinical Research & Services department. A Monitoring Plan has to be written based on a standardized template that provides monitors with the tools and expectations to monitor studies consistently, thoroughly and in accordance with the clinical investigation plan. Ottobock commits to implement a grievance mechanism for trial participants for the unlikely event that any of our standards, guidelines, principles or requirements are violated. This way we want to provide all participants with a platform to raise any concerns and complaints. Trial participants are entitled to file a complaint concerning their treatment before, during and after a trial. Trial participants can also file a complaint anytime to the Clinical Lead.

6. Registration and disclosure requirements

Ottobock intends to disclose all trial results within a twelve-month period after completion of the study. Therefore, the results of terminated trials are published on the website, in credible databases, such as the EU Clinical Trials Register, and in peer reviewed journals. Not only are terminated trial results published, but Ottobock aspires to pre-register all clinical trials in credible, publicly available databases. Ottobock also intends to make raw data available to third parties.

The management and all executives are responsible to act in accordance with this statement. They guide all employees as a role model and through their behavior.

Vienna, 03 Jan 2024

Place, Date

Dr. Andreas Hahn, Corporate Vice President Clinical Research and Services