smart medication

At the forefront of developing pioneering advances in gene therapy: Conceptualization and implementation of an innovative software platform (“Gene”) for gene therapy in hemophilia

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Background

In the treatment of rare diseases, gene therapies will strongly increase in importance. The complex process of qualification of treatment centers, preparation of patients for therapy, implementation of treatment and subsequent follow-up, including registry reporting can only be implemented with an integrated software tool.

Objectives

The software platform „Gene“ supports the collaboration of treatment centers in gene therapy of patients with severe hemophilia according to the “hub & spoke model” recommended by medical societies. There is a formalized division of tasks between the centers, i.e. various necessary activities are assigned to either a „hub“ or a „spoke“ center. The treating physician is guided by the software through the treatment process in a structured way, whereby the requirements of the regulatory authorities (EMA, GBA) are documented in a quality-assured manner so that treatment and outcome data to proof the benefit of the therapy is collected and can be verified.

Methods and results

Gene offers functions for secure collaboration and communication across centers, facilitating the exchange of information along the patient‘s journey from preparation to follow-up. In addition, the patient‘s treatment history is linked to the smart medication digital diary in a patient file via secure interfaces. Treatment data from gene therapy can be reported to clinical registries and used for non-interventional studies.

Conclusion

The complex process in gene therapy requires an integrated software tool. The focus should be on collaboration between the service providers to ensure optimal preparation, therapy implementation and follow-up of patients in gene therapy.

HUB and SPOKE requirements implemented in GENE