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## Development of an integrated electronic data collection and analysis system in radiation oncology: workflow characterization, system design, implementation and verification using the clinical example of pancreatic cancer

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In radiation oncology, where treatment concepts are elaborated in interdisciplinary collaborations, handling decentralized, voluminous, heterogeneous amounts of data efficiently is crucial, yet challenging, for an optimal treatment of the patient as well as for research itself. Hence, combining patient data from all involved information systems is inevitable for analyses. Therefore, a documentation and data management system was developed and integrated in the clinical environment for electronic data capture.

The main goal of using an electronic evaluation system is to reduce time and effort conducting clinical analyses. In particular with regard to prospective clinical trials and evaluations with large patient groups the system replaces the manual and normally extensive process of gathering individual patient data and preparing it for analysis. Time consuming tasks, such as retrieving image scans and patient records, are omitted by a robust storage and standard communication protocols.

The system offers not only a documentation infrastructure but also the foundation for advanced research that exceeds the conventional approach for analyses. Clinical researchers are supported by integrating state of the art analysis tools in routine evaluations. An analysis workflow was characterized and verified using the clinical example of pancreatic cancer. Further, a concept was proposed to take the next step and build a workflow management infrastructure.

Regarding the pancreatic cancer analyses a total number of 783 patients were documented into the professional, web-based documentation system. Information about radiation therapy, diagnostic images and dose distributions were imported. The present work demonstrates feasibility of a semi-automated workflow, which will be continuously optimized to eliminate manual steps in matching and segmentation. The main aim to reduce time and effort for future clinical trials was successfully achieved. Analysis tools were integrated into the existing patient database, to provide an automated procedure for extracting quantitative parameters to assist fast analysis. Validation on the cohort of patients with pancreatic cancer demonstrated data well in accordance with previously published data, and could contribute to in-house optimization of subsequent study concepts based on an improved and validated target volume definition.

The web-based system was designed and implemented to plan, tailor and conduct (multicenter) clinical trials and evaluations, thereby, reaching the best clinical performance and enhancing interdisciplinary and clinical research. It has become apparent that the benefits of digital data management and analysis lie in the central storage of data and reusability of analysis results. The system as of today simplifies scientific research work, ensures a better quality of clinical trial evaluation and ultimately supports the evaluation of treatment concepts.