SUCCESS STORY

UNIVERSITY HOSPITAL JENA

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mint Lesion™

NEXT-LEVEL WORKFLOW OPTIMIZATION IN CLINICAL TRIALS AT THE UNIVERSITY HOSPITAL JENA

Helping to establish a clinical trial center from the ground up is a challenge on multiple levels – a challenge, however, that Laura Graziani and Elisabeth Lammers from the University Hospital Jena have skillfully mastered. Today, the clinical trial center in Jena is responsible for up to 40 trials at a time and has made a name for itself with sponsors and CROs due to its excellent support and evaluation of trials. mint Lesion™ plays an essential role on this journey: since 2015, clinical trials in Jena have been evaluated and managed with the software solution.

Ms. Graziani, study coordinator, and Ms. Lammers, study assistant and MTRA, have been with Jena's clinical trial center since the very beginning. They had to start from scratch: various senior physicians were responsible for clinical trials, there was no overview and no uniform knowledge base of how to handle trials. Ms. Graziani remembers: "We first centralized everything in our office and had to learn what it actually meant to conduct clinical trials step by step: How are clinical trials assessed and evaluated? How can you measure therapeutic success?" Ms. Lammers adds, "The problem was that we didn't know what to do with terms like baseline, nadir, tumor response or timepoint." In the beginning, intricate evaluation criteria such as RECIST or Cheson also added to the complexity of the situation.

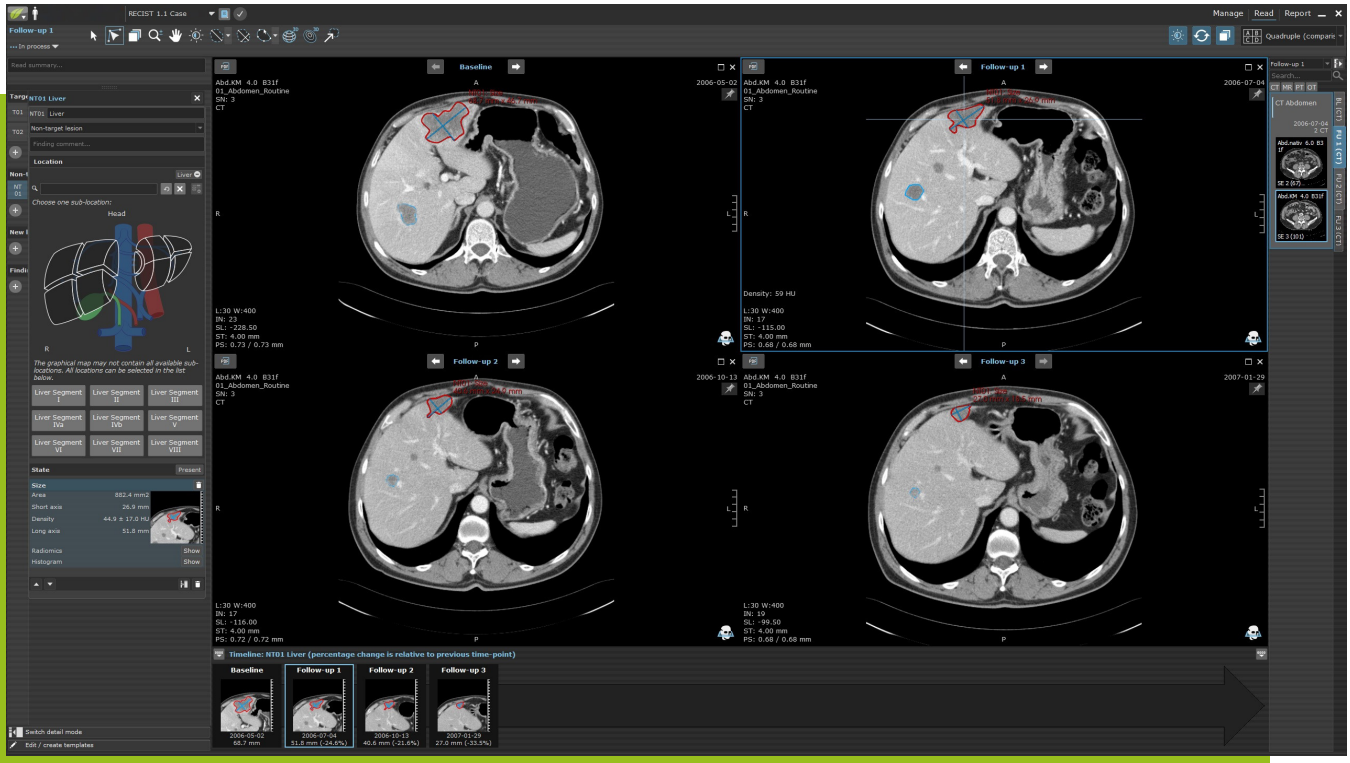
When a physician performs reads with mint Lesion™ for the first time, they can immediately see whether the results are coherent, since the software solution guides them through the read process and directly highlights non-conformities. This has greatly improved the objectivity, validity, and quality of our trials.

Elisabeth Lammers

In the process of centralizing the trial documentation and setting up the clinical trial center, it was essential to acquire a basic knowledge of trial processes. The team read up on all aspects of clinical trials and tried to standardize everything concerning evaluation criteria: "The first thing we did – and we certainly weren't the only ones – was to create Excel spreadsheets," recalls Ms. Graziani. Evaluations were done manually, sometimes with worksheets that sponsors had provided them with. However, this did not lead to the desired overview: "I remember that there were a lot of problems at the beginning because the formulas in these tables were sometimes incorrect. This messed up all the evaluations, so that the physicians then had to be asked to evaluate the follow-up examinations once more." This process was extremely inefficient and irksome; a lot of time was lost.

The question "How can we improve this process?" quickly arose, and so Ms. Lammers and Ms. Graziani both participated in additional trainings to become study assistants. But "neither then, nor when we looked for it, could we find anything concerning the technical side of radiological evaluations," explains Ms. Graziani. It was Prof. Ulf Teichgräber, Director of the Institute of Diagnostic and Interventional Radiology, who finally provided the answer to their question. Ms. Graziani continues: "We are lucky to have a boss who is very interested in trials and who really wanted to modernize and digitalize all processes. One day he came in and said, 'Ladies, I have a solution'." That solution was mint Lesion™.

Implementing mint Lesion™ was a turning point for the clinical trial center. The software solution provides a systematic, standardized evaluation that clearly and comprehensibly prepares and graphically displays all relevant data. Sources of error such as unreliable Excel spreadsheets or calculation errors are a thing of the past in Jena, because the automatic conformity checks that are carried out during the read process ensure the objectivity and quality of the results.



Driven by Prof. Teichgräber's desire for digitalization and Ms. Lammers, who has been the central contact person for everything related to mint Lesion™ since its introduction, the software has established itself as an indispensable reporting tool. However, at the beginning, a little bias on the physicians` side still had to be overcome: "The radiologists work with millions of software programs that support their daily business. Any additional software is looked at with skepticism. But right from the start, it could be observed that the radiologists were able to work with the program very quickly," emphasizes Ms. Lammers.

Today, Ms. Lammers knows the program inside out and reduces new users` reservations. Her commitment makes the initial training and familiarization with the software even easier, since all radiologists in Jena have to perform reads with mint Lesion™ and work on clinical trials. And if there are any start-up difficulties, it's clear who to turn to: "I move from one workstation to another like Superwoman, because everyone knows that if there seem to be issues, all they have to do is give me a shout and everything will work out."

Ms. Lammers' and Ms. Graziani's expertise is particularly convincing to the numerous sponsors they have worked with over the years. Discussing the setup of new trials usually only takes a few minutes, as the use of mint Lesion™ has massively reduced the administrative workload: "It is becoming increasingly common for sponsors to exchange information with each other, and they know that when there's a mint Lesion™ report on the table, they can be certain that it is of substance," says Ms. Lammers. "Word has spread that we use mint Lesion™, and there isn't a single setup meeting where I don't rave about the software."

In the past, there were always discrepancies between the trial-related reports and the clinical reports. This has now been completely eliminated by mint Lesion™. The monitors no longer ask, "Why are there two different assessments?" since there is only one assessment and that ensures the objectivity of the examination.

Laura Graziani

mint Lesion™ knows all evaluation criteria and alerts the user if something is not compliant during the read process. Consequently, the software solution actively counteracts errors and can ensure the validity and completeness of the report. Ms. Graziani is particularly pleased with this feature; in the past, radiologists used small memos to read up on criteria, but today they "can look up the rules of the evaluation criteria in a wonderfully understandable and comprehensible way, even in the middle of a read. We've rarely found it described this well in literature." Thus, objective reports are generated in a fraction of the time it used to take. "The software has made us much more efficient and much faster; it's a next-level workflow optimization," Ms. Graziani says. "Thanks to this, we can naturally conduct more trials."

Word has also spread within the hospital about the benefits of context-driven structured reporting, which enables integrated diagnostics across disciplines. Gradually, clinicians from other departments approached the radiology department and wanted their patients to be diagnosed with the software as well. So, since October 2020, mint Lesion™ has also been used in clinical routine: "All prostate reports are now solely read with mint Lesion™, and that's quite a few. The next project is that we want to read the mammary MRIs with mint," confirms Ms. Lammers. In the medium term, all oncology patients will experience this type of systematic reporting, which will increase the treatment safety during the course of the disease.

Image sources: Universitätsklinikum Jena
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