mint Lesion™

EFFICIENT WORKFLOWS AND REPORTING COMPLIANT WITH RECIST AND OTHER QUANTITATIVE IMAGING STANDARDS IN CANCER RESEARCH AND CLINICAL PRACTICE

Modern targeted therapies play an increasingly important role in the treatment of cancer patients in the era of personalized medicine. Clinical studies already demonstrated considerable tumor response (increased overall survival) under treatment with new agents such as Sorafenib in HCC and RCC, or Imatinib in GIST. In the face of these modern targeted therapies and increasingly multi-modal therapy approaches, new challenges and opportunities arise for oncological procedures and radiological image-based diagnoses.

A major pitfall in tumor response monitoring is the increasing incidence of mixed response in targeted therapies. A typical example is the treatment with Vemurafenib in metastatic melanoma with specific B-RAF mutation. Response to Vemurafenib is typically not durable because of suddenly developing resistances. An early detection of disease progression provides improved outcome of subsequent therapies, e.g. with the monoclonal antibody Ipilimumab.

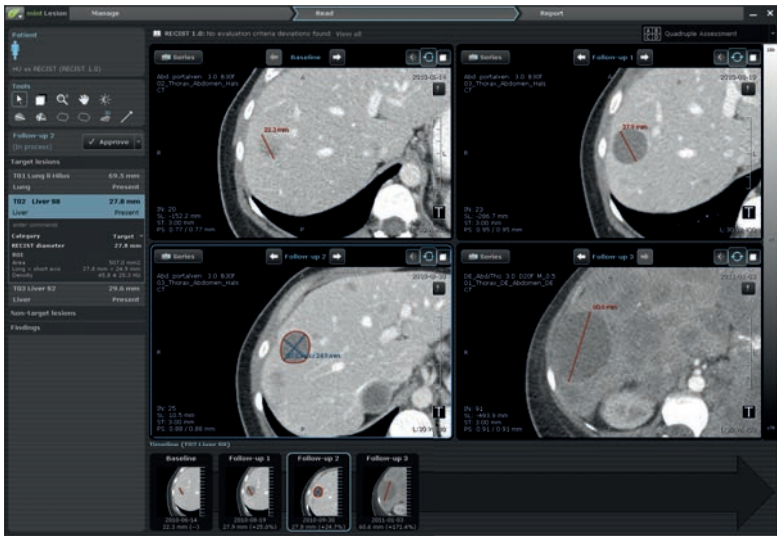

Figure 1:

The mint Lesion Read Module

A 44-year-old patient with metastatic melanoma treated with Vemurafenib was radiologically assessed according to the RECIST 1.1 guidelines. A first follow-up CT scan eight weeks after treatment start (Baseline) showed mixed response, a radiological status where both regressive and progressive lesions coexist: one target lesion (T01) indicated good treatment response, while two further target lesions (T02, T03) displayed significant increase in size (c.f. Table 1). The Overall Response according to RECIST criteria is 'Partial Response', due to a Target Sum decrease of more than 30%. After another six weeks of treatment, however, the second follow-up CT examination showed rapid progression of all target lesions; Overall Response was now 'Progressive Disease'.

In the above example, the strong regression of a single lesion could mislead the reader to assess the treatment as partial remission, or the overall disease as stable. Also, in this case, a strict application of RECIST could encourage the reader in her or his finding. Nevertheless, disease progression was assessed six weeks too late by RECIST. A different selection of RECIST targets and non-targets at Baseline might have resulted in an earlier assessment of disease progression.

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Radiological therapy response assessment is challenging, particularly in cases like the above, but proper response assessment and reporting are crucial. An incomplete assessment or a delayed assessment of disease progress might result in a late switch of therapy, which in turn might implicate serious consequences for the patient. Bearing in mind challenging cases such as mixed responders, and generally the sustained development towards targeted therapies that will make cancer an increasingly chronic disease in the long run, an obvious question is, how should radiologists deal with this?

A computer-guided, standardized reading workflow can address these new demands, for instance by automating routine tasks and by improving team collaboration of longitudinal reads aiming at therapy monitoring. Surveys show that the overwhelming majority of both oncologists and radiologists believe that quantitative tumor assessment is important for oncology patient care, but that formal response assessment is often not conducted due to cumbersome and inefficient workflows. The vast majority (86%[1]) of surveyed radiologists agreed that providing tumor measurements slows workflow, and that they would be more likely to do so if they had software to simplify the procedure.

In 2009, radiologists and computer scientists of the German Cancer Research Center (DKFZ) started a close collaboration to design and develop a workflow software solution named mint Lesion, which by now is commercially available from a DKFZ spin-off named Mint Medical. mint Lesion is specifically designed to streamline the read process: it covers management of patient cohorts in the context of disease and treatment, assessment of lesions with respect to the overall patient treatment course,

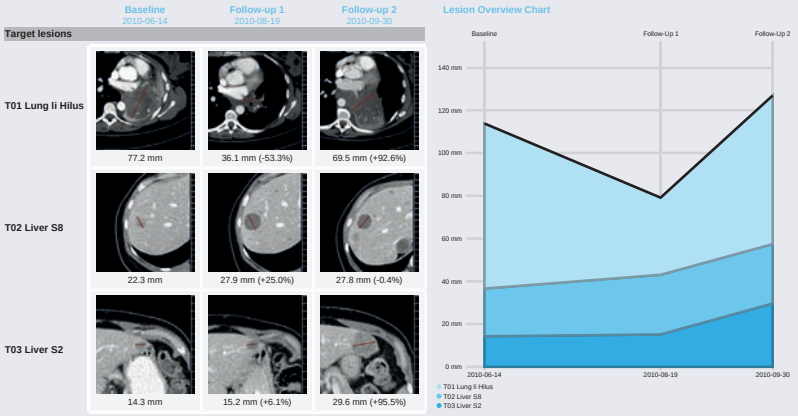

Figure 2: An automatically generated, consolidated overview of patient treatment course illustrates significant image instances and measurement data.

RECIST Report - ECR Patient 1967

	Baseline 2010-06-14	Follow-up 1 2010-08-19	Follow-up 2 2010-09-30
Target lesions		All progress values are relative to their previous value.	
T01 Lung li Hilus	77.2 mm	36.1 mm (-53.3%)	69.5 mm (+92.6%)
T02 Liver S8	22.3 mm	27.9 mm (+25.0%)	27.8 mm (-0.4%)
T03 Liver S2	14.3 mm	15.2 mm (+6.1%)	29.6 mm (+95.5%)
Evaluation			
Target sum	113.8 mm	79.1 mm (-30.5%)	126.9 mm (+60.4%)
Target response	Undefined	Partial Response	Progressive Disease
Timepoint response	Undefined	Partial Response	Progressive Disease

Table 1: Mixed Response of a melanoma patient under Vemurafenib treatment.

statistical response evaluation in line with response criteria, and consistent and comprehensive automated reporting. Figure 1 illustrates the longitudinal assessment of the example patient case by means of mint Lesion.

Besides reproducible measurements, assessment notes, treatment outcome statistics for patient cohorts and individual patients, mint Lesion provides an automatically generated, consolidated visual and textual overview of a single treatment course (c.f. Figure 2). Graphical charts help to identify the dimension of tumor load change with respect to baseline, nadir and previous exams, and the prevalence of mixed response, like in the above example patient case. By such means, the standardization of the read workflow contributes to the assessment quality of longitudinal follow-up sequences, and provides comprehensible information to an interdisciplinary assessment of the therapy response in a tumor board.

1 Jaffe TA, et al., AJR 2010; 195:W19-W30

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