

Editorial on Non-Imaging Biomarkers

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Editorial

Biomarkers and response criteria are used in imaging-based clinical trials to determine the tumor's response to therapy. Although both words are often used interchangeably, the distinction between the two is crucial in a clinical trial involving imaging. Imaging biomarkers are often the key contributors to the endpoints of clinical trials, but they are not the same.

A biomarker is a biological trait that can be objectively tested and analysed to determine whether a process is normal or pathological. A biological feature that can be detected on an image is known as an imaging biomarker.

- Imaging biomarkers can be anatomical (e.g., the largest diameter of a large round lesion = structural information) or functional (e.g., the largest diameter of a large round lesion = structural information) (i.e. looking for physiological aspects of the tumour in such as oxygenation levels, cellularity or vascularity)
- Imaging biomarkers may be descriptive (i.e., "a nodule is present in

the lung") or quantitative (i.e., "the longest diameter of the nodule decreased by 5mm after treatment as opposed to its size before treatment."). Several imaging biomarkers may play a role in one or more response criteria.

The Response Evaluation Criteria in Solid Tumors (RECIST) uses multiple imaging biomarkers, for example. The scale of the target lesions' longest axial diameter is the first quantitative imaging biomarker used by RECIST.

Another RECIST imaging biomarker is a qualitative one that tracks any new lesions that occur in the image; its assessment is a binary and subjective outcome.

The final imaging biomarker in the RECIST method is a subjective measure of unequivocal progression of non-target lesions. ("Has there been a noticeable rise in all of these non-target lesions?")

The simultaneous monitoring of these three imaging biomarkers constitutes the therapeutic response as described by RECIST. The therapeutic tumour response can then be tested using the RECIST criterion on different imaging timepoints of the same patient in a clinical trial.

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