

TABLE 12.1 The Demetri Study of Gastrointestinal Stromal Tumors

	Nature of Objective Response (% of Subjects)	
	400 mg Imatinib	600 mg Imatinib
Complete response	0	0
Partial response	49.3	58.1
Stable disease	31.5	24.3
Progressive disease	16.4	10.8
Could not be evaluated	2.7	6.8

RECIST criteria result in poor correlations of objective response with survival (44).

The results from the clinical trial of Demetri et al. (45) are indicated in Table 12.1. The responses were assessed by PET scanning, followed by a confirmatory scan at least 28 days later. These results demonstrate that about half the subjects showed a PR (partial shrinkage) while about a quarter of the subjects showed SD. Only about 14% of the subjects experienced increases in tumor size. There were no significant differences in objective response between the two doses of imatinib. Figure 12.3 discloses representative PET scans (raw data) from one particular subject, where scans were taken at baseline, after 1 month of imatinib treatment, and after 16 months of imatinib treatment. The figure reveals a dramatic reduction and near-disappearance of the pelvic-level signal arising from the tumors.

<sup>44</sup>Benjamin RS, Choi H, Macapinlac HA, et al. We should desist using RECIST, at least in GIST. *J. Clin. Oncol.* 2007;25:1760–4.

<sup>45</sup>Demetri GD, von Mehren M, Blanke CD, et al. Efficacy and safety of imatinib mesylate in advanced gastrointestinal stromal tumors. *New Engl. J. Med.* 2002;347:472–80.

<sup>46</sup>van Persijn van Meerten EL, Gelderblom H, Bloem JL. RECIST revised: implications for the radiologist. A review article on the modified RECIST guideline. *Eur. Radiol.* 2010;20:1456–67.

<sup>47</sup>Suzuki C, Jacobsson H, Hatschek T, et al. Radiologic measurements of tumor response to treatment: practical approaches and limitations. *Radiographics* 2008;28:329–44.

### c. Objective Response—van Meerten’s Example of PR

In a description of lung tumors, occurring with the metastasis of uterine cancer, van Persijn van Meerten et al. (46) provide images of tumors assessed by objective response, according to the RECIST criteria. In Fig. 12.4, panels a and b show CT scans *before chemotherapy* (baseline data), while panels c and d show scans *after chemotherapy*. The arrows in panels a and c point to target lesions, while the arrows in b and d point to nontarget lesions. The term “target lesions” refers to specific tumors that the investigator has decided to measure repeatedly during the course of the study.

All of the images are of lung tumors from the same woman being treated for uterine cancer. In comparing a and c, it is easy to see that the target lesion (arrow) has shrunk but has not disappeared. In comparing b and d, it is easy to see that one of the nontarget lesions (arrow) has actually increased in size. The patient’s response was classified as PR. In other words, the patient’s response was not classified as CR or as SD, but instead it was classed as PR.

### d. Objective Response—Example of PD

The data in Fig. 12.5 are used to illustrate the endpoint of PD, also known as disease progression. This provides a clear-cut example of the application of the RECIST criteria to the endpoint of PD. In a description of a man with rectal cancer, Suzuki et al. (47) provide images of tumors that have metastasized to the lungs