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A multidisciplinary approach is required to increase the quality of phase II/III clinical studies on biotherapies in oncology

We have previously published an appropriate score in order to evaluate the quality of phase II studies on biochemotherapy validated through the screening of 334 papers published from 1998 to 2002 [1]. In that manuscript, we have concluded that the very wide diversity in modalities of conducting and reporting clinical trials of biotherapies of solid tumours and the presence of some methodological pitfalls (such as inclusions of low performance status patients, lack of biological end points etc.) suggest that the methodological standards for conducting and publishing clinical trials in biotherapies should be improved to enhance the reliability of the body of published data. On the basis of these considerations, we have recently performed an update of this survey. Overall, we have analysed data on 797 studies collected by hand searching of all phase II/III clinical trials of biotherapies in solid tumours published from 1998 to 2006 in seven distinguished journals. Among statistical significant associations, the strongest relationship emerged between the quality of studies and the presence of a multidisciplinary team in the authorship ($P < 0.0001$) (Table 1). Noteworthy, the scores were always >75 points if more than two disciplinary authorships were present. By contrast, more than half of nonmultidisciplinary studies scored <40 points, even though they were published in high impact factor journals (Table 1).

It has been already described in clinical trials on chemotherapy in breast cancer that the presence of an identifiable statistical plan, more frequently related to the presence of a multidisciplinary authorship (clinicians and statisticians) in the authorship, associates with an overall high quality of a clinical trial [2, 3]. Our observation is a clear evidence that multidisciplinary in biotherapy studies in oncology can guarantee a good design, conduction and reporting of such studies. Any efforts should be done to promote and/or stimulate multidisciplinary teams (clinicians, statisticians, basic and translational researchers, etc.).

Table 1. Quality index of manuscripts on phase II/III clinical trials of biotherapies in solid tumours

$P < 0.0001$	NM (1 discipline)	Low multidisciplinary (two disciplines)	High multidisciplinary (more than two disciplines)
QI ≥ 80	29	152	201
40 < QI > 80	101	65	24
QI ≤ 40	189	36	0

QI, Quality Index; NM, nonmultidisciplinary.

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