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**Objective response rate assessment in oncology: Current situation and future expectations**

Aykan NF *et al.* Objective response rate assessment in oncology

Nuri Faruk Aykan, Tahsin Özatlı

**Abstract**

The tumor objective response rate (ORR) is an important parameter to demonstrate the efficacy of a treatment in oncology. The ORR is valuable for clinical decision making in routine practice and a significant end-point for reporting the results of clinical trials. World Health Organization and Response Evaluation Criteria in Solid

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Objective Response Rate Assessment in Oncology: Current Situation and Future



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## Response evaluation criteria in solid tumors - Wikipedia

[https://en.wikipedia.org/wiki/Response\\_Evaluation\\_Criteria\\_in\\_Solid\\_Tumors](https://en.wikipedia.org/wiki/Response_Evaluation_Criteria_in_Solid_Tumors) ▼

**Response** evaluation criteria in solid tumors (RECIST) is a set of published rules that define when tumors **in cancer** patients improve ("respond"), stay the same ("stabilize"), or worsen ("progress") during treatment. The criteria were published in February 2000 by an international collaboration including the European Organisation for Research and Treatment of **Cancer** (), National **Cancer** ...

## Clovis Oncology Presents Initial Results from the Ongoing ...

<https://www.businesswire.com/news/home/20181019005012/en/Clovis-Oncology-Presents...> ▼

Oct 19, 2018 · The data show a 44% confirmed **objective response rate** (ORR) by investigator **assessment** in 25 RECIST \* /PCWG3 \*\* **response**-evaluable patients with a BRCA1/2 alteration. The median duration of ...

## Endpoint Considerations for Immuno-Oncology Research

<https://www.immunooncologyhcp.bmsinformation.com/clinical-expectations/end-point...> ▼

Endpoint Considerations for Immuno-Oncology Research Immuno-Oncology research: reshaping measures of clinical benefit. The criteria currently used to assess potential benefit of **cancer** therapies are based on surgery, radiation therapy, and chemotherapy. 1 Immuno-Oncology is a fundamentally different way to fight **cancer**. 2 As a new area of research, a more comprehensive approach to endpoint ...

## [PDF] Efficacy endpoints in Oncology - Lex Jansen

<https://www.lexjansen.com/phuse/2013/is/IS01.pdf>

Efficacy endpoints **in Oncology** Angelo Tinazzi, Cytel Inc., Geneva, Switzerland ABSTRACT The evaluation of efficacy **in oncology** studies, in particular for solid tumors, is pretty standard and well defined by several regulatory guidance (e.g. EMA and FDA), including some specific **cancer** type guidance (e.g. NSCLC from FDA).

## [Advance directives in dermatology: The current ...

[https://www.researchgate.net/publication/301337185\\_Advance\\_directives\\_in\\_dermato...](https://www.researchgate.net/publication/301337185_Advance_directives_in_dermato...)

[Advance directives in dermatology: The **current situation and future prospects**] ... i.e. a **response rate** of 31 %. ... and at 12 weeks with the use of the Functional **Assessment of Cancer** ...

## Phase 2 Objective Response Rate and Survival Data for ...

<https://news.bms.com/press-release/rd-news/phase-2-objective-response-rate-and...> ▼

Oct 30, 2014 · The estimated one-year survival rate was 41% (95% CI = 31.6, 49.7) and mOS was 8.2 months (95% CI = 6.05, 10.91). An additional 26% of patients had stable disease with a median duration of six months (95% CI, 4.73, 10.91) giving a disease control rate (defined as partial response + ...





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## Patient relevant endpoints in oncology: current issues in ...

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3901346>

Patient relevant endpoints in **oncology: current** issues in the context of early benefit **assessment** in Germany Inna Dabisch , 1 Jürgen Dethling , 2 Charalabos-Markos Dintsios , 1 Melanie Drechsler , 3 Daniel Kalanovic , 4 Peter Kaskel , 5 Frank Langer , 6 Jörg Ruof , 7 ...

**Cited by:** 9**Author:** Inna Dabisch, Jürgen Dethling, Charalab...**Publish Year:** 2014

## Clinical Trial Efficacy Endpoints | BioOncology

<https://www.biooncology.com/clinical-trials/efficacy-endpoints.html> ▼

The following table shows a number of efficacy endpoints. Each of these endpoints is associated with certain advantages and limitations. Although the endpoint definitions provided here are from FDA guidance, please note that individual clinical trials may use different definitions.

## [PDF] Clinical Trial Endpoints for the Approval of Cancer Drugs ...

<https://www.fda.gov/media/71195/download>

Clinical Trial Endpoints for the Approval of **Cancer** Drugs and Biologics . Guidance for Industry . U.S. Department of Health and Human Services Food and Drug Administration

## [PDF] Objective response rate is a possible surrogate endpoint ...

[https://www.gynecologiconcology-online.net/article/S0090-8258\(17\)30770-9/pdf](https://www.gynecologiconcology-online.net/article/S0090-8258(17)30770-9/pdf)

**Objective response rate** is a possible surrogate endpoint for survival in patients with advanced, recurrent ovarian **cancer**☆ Mohammed Kashif Siddiquia, Jerzy Tyczynskib,1, Ankit Pahwaa, Ancilla W. Fernandesc,\* a PAREXEL International, Chandigarh, Chandigarh, India b Global Medical Evidence and Outcomes Research, AstraZeneca, Gaithersburg, MD, USA c Health Economics and Outcomes ...

## FDA Approves Keytruda (pembrolizumab) plus Lenvima ...

<https://www.drugs.com/newdrugs/fda-approves-keytruda-pembrolizumab-plus-lenvima...> ▼

The major efficacy outcome measures were objective response rate (ORR) and duration of response (DOR) by independent radiologic review committee (IRC) using RECIST 1.1. Among the 108 patients



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## Clinical Trial Efficacy Endpoints | BioOncology

<https://www.biooncology.com/clinical-trials/efficacy-endpoints.html> ▾

The following table shows a number of efficacy endpoints. Each of these endpoints is associated with certain advantages and limitations. Although the endpoint definitions provided here are from FDA guidance, please note that individual clinical trials may use different definitions.

## Outcomes and endpoints in trials of cancer treatment: the ...

<https://www.sciencedirect.com/science/article/pii/S1470204514703754>

Outcomes and endpoints in trials of **cancer treatment**: the past, present, and future ... phase 3 trials. 46 A review of 89 trials of targeted therapies in six **cancer** types showed that **objective response rate** correlated with high non-progression **rates** and ... of life requires the same rigour as does the **assessment** of **objective response rate** and ...

Cited by: 100

Author: Michelle K Wilson, Katherine Karakasis, A...

Publish Year: 2015

## [PDF] EFFICACY ENDPOINTS IN ONCOLOGY

[https://www.cytel.com/hubfs/0-library-0/pdfs/IS01\\_PPT.pdf](https://www.cytel.com/hubfs/0-library-0/pdfs/IS01_PPT.pdf)

'70: **Objective** (tumor) **Response Rate** (ORR) ... (best **response** prior to **current assessment**) A 20% increase in the sum of all lesions' measurements (mm) ... Ji Yu, P Slagle, "**Objective** tumor **response** and RECIST criteria in **cancer** clinical trials," in MWSUG, 2011. Geneva Branch . Cytel Inc. - Confidential 11 .

## Clinical Data Presented from PIVOT-02 Study of ...

<https://ir.nektar.com/news-releases/news-release-details/clinical-data-presented-pivot...> ▾

Sep 26, 2019 · Confirmed overall **objective response rate** (ORR) was 13% ... they are based only on our **current** beliefs, **expectations** and assumptions regarding the **future** of our business, **future** plans and strategies, anticipated events and trends, and other **future** conditions. Because forward-looking statements relate to the **future**, they are subject to inherent ...

## [PDF] Objective response rate is a possible surrogate endpoint ...

[https://www.gynecologiconcology-online.net/article/S0090-8258\(17\)30770-9/pdf](https://www.gynecologiconcology-online.net/article/S0090-8258(17)30770-9/pdf)

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## [PDF] Efficacy endpoints in Oncology - Lex Jansen