

# MEDICINA

## Področje: 3.04 – Onkologija



Področje onkologije je izjemno hitro razvijajoče področje, ker je vsaka aplikativna novost pri zdravljenju raka zelo dobrodošla. Ponavadi je tudi družbeno zaznavna, saj se taki dosežki hitro prebijejo v dnevno časopisje, s tem da bolniki redno spremljajo nova dognaja.

Na tem področji so raziskave usmerjene v bazične in klinične, ter translacijske. V Sloveniji je razmeroma veliko raziskav s področja onkologije, ki obsegajo vse našeta področja raziskav v onkologiji. Glede na to so raziskave v Sloveniji v trendu raziskav po svetu.

Mnoge raziskave so povezane z mednarodnimi centri, v mednarodnih projekth, bilateralnih izmenjavah in mednarodnih kliničnih raziskavah; tako akademskih, kot tudi farmacevtskih. Tako so mnogi izjemni dosežki rezultat teh mednarodnih povezav, kjer naši strokovnjaki sodelujejo in so zato soavtorji v pomembnih in odmevnih objavah. Žal pa je v onkologiji izjemno malo vključevanja v EU projekte. Razlog za to je predvsem izjemno zahtevna birokracija pri vodenju takih projektov in pomanjkanje podpore pri vodenju projektov s strani inštitucij, kot so Klinični center, Onkološki inštitut in Medicinska fakulteta UL.

Opažam pa, da je zelo malo izjemno dobrih publikacij s področja onkologije, ki so plod dela domačih skupin, trdega večletnega dela. Pogrešamo raziskave, ki bi bile injicirane iz Slovenije ter vključevale tuje raziskovalce.

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## Področje: 3.04 – Onkologija

**Dosežek 1:** ŠERUGA, Boštjan, STERLING, Lynn, WANG, Lisa, TANNOCK, Ian. Reporting of serious adverse drug reactions of targeted anticancer agents in pivotal phase III clinical trials. *J. clin. oncol.*, 2010, vol. 29, no. 2, str. 174-185, doi: 10.1200/JCO.2010.31.9624

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JOURNAL OF CLINICAL ONCOLOGY ORIGINAL REPORT

### Reporting of Serious Adverse Drug Reactions of Targeted Anticancer Agents in Pivotal Phase III Clinical Trials

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Author disclosures of potential conflicts of interest and author contributions are found at the end of this article.

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**ABSTRACT**

**Purpose**  
Oncologists prescribe anticancer drugs based on results of phase III randomized clinical trials (RCTs), but some safety concerns appear only later in updated drug labels. Here, we analyze adverse drug reactions (ADRs) of targeted anticancer agents from updated drug labels and their reporting in corresponding pivotal RCTs.

**Methods**  
We searched the US Food and Drug Administration (FDA) Web site for approved targeted anticancer drugs with updates of their labels related to safety in 2008 and 2009 and at least one RCT referenced in the updated drug label. For each drug, serious ADRs, including potentially fatal ADRs, were identified from the updated label. Published reports of RCTs referenced in the label were searched to determine whether they described these ADRs.

**Results**  
We identified 12 eligible targeted anticancer agents with 36 corresponding RCTs referenced in updated drug labels. There were 76 serious ADRs reported in updated drug labels, and 50% (n = 38) were potentially fatal. Of these, 39% (n = 30) of all serious ADRs and 39% (n = 15) of potentially fatal ADRs were not described in any published report of RCTs, whereas 49% and 58%, respectively, were not described in initial drug labels. After a median 4.3 years between initial approval and update of drug labels, 42% (n = 5) of targeted cancer agents acquired one or more boxed warnings (the highest level of FDA alert).

**Conclusion**  
Published reports of pivotal RCTs and initial drug labels contain limited information about serious ADRs of targeted anticancer agents. Rare but serious ADRs may be important causes of morbidity and mortality in general oncologic practice.

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Dr Boštjan Šeruga je internistični onkolog na Onkološkem inštitutu Ljubljana. V času njegovega izobraževanja v Kanadi, pri prof. Tannocku, je imel priložnost delovati v izredno produktivnem okolju, kar je izkoristil in uspel rezultate svojega dela objaviti v dveh izjemnih publikacijah. Kot je razvidno iz SICRISA se njegova serija izjemnih publikacij nadaljuje, še vedno samo v sodelovanju s kanadsko skupino.

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## Področje: 3.04 – Onkologija

**Dosežek 2:** PAGANI, Olivia, SENUKS, Elzbieta, WOOD, William Bill, ČUFER, Tanja. International guidelines for management of metastatic breast cancer : can metastatic breast cancer be cured?. *J. Natl. Cancer Inst.*, 7 Apr 2010, vol. 102, issue 7, str. 456-463, doi: [10.1093/jnci/djq029](https://doi.org/10.1093/jnci/djq029).

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### COMMENTARY

## **International Guidelines for Management of Metastatic Breast Cancer: Can Metastatic Breast Cancer Be Cured?**

Olivia Pagani, Elzbieta Senkus, William Wood, Marco Colleoni, Tanja Cufer, Stella Kyriakides, Alberto Costa, Eric P. Winer, Fatima Cardoso, on behalf of the ESO-MBC Task Force

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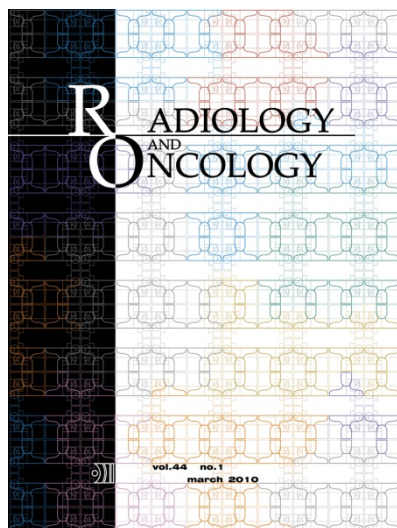
Članek v katerem je sodelovala prof. Čufer kot članica ESO-Metastatic Breast Cancer Task force. Članek je velikega pomena za vzpostavljanje mednarodnih smernic pri zdravljenju metastatskega raka dojke. Prof. Čufer je kot mednarodno priznan strokovnjak s področja internistične onkologije vpeta v mednarodne strokovne organizacije, poleg v European School of Oncology, tudi v ASCO (American Society of Clinical Oncology) kjer je IAC Chair (predsednik skupine za mednarodne stike – International Affairs Committee)

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## Področje: 3.04 – Onkologija

**Dosežek 3:** *Radiology and oncology*. Serša, Gregor (glavni urednik 1998-). Ljubljana: Association of Radiology and Oncology, Slovenian Medical Society - Section of Radiology; [Zagreb]: Croatian Medical Association - Croatian Society of Radiology, 1992-. ISSN 1318-2099. [http://www.onko-i.si/raziskovanje\\_in\\_izobrazevanje/strokovne\\_in\\_znanstvene\\_publikacije/radiology\\_and\\_oncology/arhiv\\_elektronsko\\_dostopnih\\_stevilk/index.html](http://www.onko-i.si/raziskovanje_in_izobrazevanje/strokovne_in_znanstvene_publikacije/radiology_and_oncology/arhiv_elektronsko_dostopnih_stevilk/index.html). [COBISS.SI-ID [32649472](http://www.onko-i.si/raziskovanje_in_izobrazevanje/strokovne_in_znanstvene_publikacije/radiology_and_oncology/arhiv_elektronsko_dostopnih_stevilk/index.html)]



Znanstvena revija, **Radiology and Oncology**, ki izhaja že 45 let, je letos pridobila faktor vpliva (1,97) in tako naredila velik skok na lestvici vpliva v akademski sferi. Izhaja v angleškem jeziku, tako da v njej objavljajo avtorji iz različnih dežel. Na področju Onkologije zavzema *Radiology and Oncology* 119. mesto med 185. revijami, kar jo uvršča v tretji kvartil (Q3).

Področja objav v *Radiology and Oncology* so tako s področja slikovne diagnostike, eksperimentalne radiologije, nuklearne medicine, klinične onkologije, radioterapije, eksperimentalne onkologije in radiofizike.

Revija je prosto dostopna, na <http://versitaopen.com>