Author’s response to reviews

Title: Comprehensive routine diagnostic screening to identify predictive mutations, gene amplifications, and microsatellite instability in FFPE tumor material

Authors:

Elisabeth Steeghs (lieneke.steeghs@radboudumc.nl)
Leonie Kroeze (leonie.kroeze@radboudumc.nl)
Bastiaan Bops (B.B.J.Tops@prinsesmaximacentrum.nl)
Leon van Kempen (l.van.kempen@umcg.nl)
Arja ter Elst (a.ter.elst@umcg.nl)
Annemiek Kastner-van Raaij (Annemiek.Kastner-vanRaaij@radboudumc.nl)
Sandra Hendriks-Cornelissen (sandra.hendriks-cornelissen@radboudumc.nl)
Mandy Hermsen (mandy.hermsen@radboudumc.nl)
Erik Jansen (erik.am.jansen@radboudumc.nl)
Petra Nederlof (p.nederlof@nki.nl)
Ed Schuuring (e.schuuring@umcg.nl)
Marjolijn Ligtenberg (Marjolijn.Ligtenberg@radboudumc.nl)
Astrid Eijkelenboom (Astrid.Eijkelenboom@radboudumc.nl)

Version: 2 Date: 20 Mar 2020

Author’s response to reviews:

Dear dr. Rice,

Thank you very much for your decision letter of our manuscript “Comprehensive routine diagnostic screening to identify predictive mutations, gene amplifications, and microsatellite instability in FFPE tumor material”.

Please find below a point-by-point explanation of our actions in response to the editor comments.

We hope you will find the carefully revised version suitable for publication.
With kind regards,
Dr. Astrid Eijkelenboom

Editor Comments:

1 - Research involving human subjects (including human material or human data) that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (http://www.wma.net/en/30publications/10policies/b3/index.html). A statement to this effect must appear in the ‘Ethics approval and consent to participate’ section of the Declarations of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.
If the need for ethics approval were waived, then please clearly state this, including the name of the ethics committee that provided the exemption, together with the reasons for the waiver, or a reference to the relevant legislation.

The statement concerning the approval by Local Ethical Committee of the Radboudumc was adjusted in the ‘Ethics approval and consent to participate’ section of the revised manuscript (line 486-487, page 24):
The study was conducted in accordance with the Declaration of Helsinki and was approved by the Local Ethical Committee of the Radboudumc (CMO 2016-2967).

2 - For all research involving human subjects, informed consent to participate in the study should be obtained from participants (or their parent or guardian in the case of children under 16) and a statement to this effect should appear in the ‘Ethics approval and consent to participate’ section of the Declarations including whether the consent was written. When reporting on such studies, individual patient data should not be made available unless consent for publication has also been obtained.
If the need for informed consent has been waived by an IRB or is deemed unnecessary according to national regulations, please clearly state this with details, including the name of the Board or a reference to the relevant legislation in the ‘Ethics approval and consent to participate’ section of the Declarations.

The need for informed consent was waived by the Local Ethical Committee of the Radboudumc, which is stated in the revised manuscript in the ‘Ethics approval and consent to participate’ section (line 487-491, page 24):
Informed consent was not applicable, as the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects. The Local Ethical Committee of the Radboudumc approved the waiver of consent. Data from patients who objected against the use of their data for scientific research were excluded from the study.
3 - In the Funding section of the Declarations please indicate the role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript. If no specific funding was received for this study, please clearly indicate this in the Funding section.

The role of the funding body in the study was added to the ‘Funding’ section of the revised manuscript (line 510-513, page 25):
This work is part of the research program Personalised Medicine which is financed by the Netherlands Organization for Health research and Development (ZonMw, project number 846001001). The funder was not involved in the study design, data collection, analysis, interpretation, or writing of the manuscript.