Author’s response to reviews

Title: Use of Ceftaroline Fosamil in Osteomyelitis: CAPTURE Study Experience

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Author’s response to reviews:

January 15, 2019

Oliver Cocks
Editor-in-Chief
BMC Infectious Diseases
RE: INFD-D-18-01748

Dear Dr Cocks,

Thank you for considering our manuscript titled, “Use of Ceftaroline Fosamil in Osteomyelitis: CAPTURE Study Experience” for publication in BMC Infectious Diseases. We have received the editorial comments and have resubmitted our manuscript and look forward to reviewer comments.

Sincerely,
Leonard B. Johnson, MD
Editorial Comments

1. Thank you for providing a list of IRB names and locations. However, Can we please request that you remove the name of the primary investigators from your supplementary file only including Site number and institutional review board name.

Response: We have removed the name of the primary investigators and have included the site number and institutional review board names and addresses.

2. At this stage, we ask that you submit a clean version of your manuscript and do not include track changes or highlighting.

Response: We have submitted a clean version of the manuscript and have not tracked or highlighted the changes that we made to the supplemental materials.

Editorial Policies

Please read the following information and revise your manuscript as necessary. If your manuscript does not adhere to our editorial requirements this will cause a delay whilst the issue is addressed. Failure to adhere to our policies may result in rejection of your manuscript. In
accordance with BioMed Central editorial policies and formatting guidelines, all submissions to BMC Infectious Diseases must have a Declarations section which includes the mandatory sub-sections listed below (Ethics approval and consent to participate; Consent to publish; Availability of data and materials, Competing interests; Funding, Authors' Contributions, Acknowledgements and Authors' Information). Please refer to the journal's Submission Guidelines web page for information regarding the criteria for each sub-section (https://bmcinfectdis.biomedcentral.com). Where a mandatory section is not relevant to your study design or article type, for example, if your manuscript does not contain any individual persons data, please write "Not applicable" in these sections.

Response: We have referred to and included a Declarations section per the Submission Guidelines on the BMC—infectious disease website. ‘Ethical approval and consent to participate,’ ‘Consent to publish,’ Competing interests,’ ‘Funding,’ ‘Author contributions,’ and ‘Acknowledgements’ subsections were included with the submission of our manuscript, as follows:

Declarations

Ethics approval and consent to participate

This study was submitted to and approved by appropriate institutional review boards (IRBs) as listed in Supplemental Table 1. This study was conducted in compliance with the International Conference on Harmonisation (ICH) Technical Requirements for Registration of Pharmaceuticals for Human Use: Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance (1996), Good Pharmacoepidemiology Practice, Health Insurance Portability and Accountability Act, 21 CFR Part 11, and any additional national or IRB requirements. Due to the retrospective nature of data collection for this study, patient written consent was waived or collected before data extraction as appropriate based on individual site IRB requirements (Supplemental Table 1).

Consent to publish

Not applicable; individual patient data are not presented.
Availability of data and material

Data reported in this manuscript are available within the article [and/or] its supplementary materials. Additional data from the CAPTURE registry may be requested at http://www.allerganclinicaltrials.com/PatientDataRequest.htm.

 Competing interests

Financial arrangements of the authors with companies whose products may be related to the present report are listed below, as declared by the authors. LBJ has received research support from Allergan. AR has served as a speaker for Allergan and Gilead. DJG has received clinical research support from Durata Therapeutics Inc (now Allergan plc).

Funding

This study was sponsored by Allergan plc (Dublin, Ireland). Neither honoraria nor payments were made for authorship. Allergan sponsored the study and funded medical writing support but did not otherwise participate in the design of the study or collection, analysis, and interpretation of data or in writing the manuscript.

Author contributions

LBJ, AR, and DLG participated in the design and conduct of the study, analysis and interpretation of the data, and drafting and reviewing the manuscript. LBJ, AR, and DLG have given final approval of the version to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors have read and approved the manuscript.

Acknowledgments

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For the 'Availability of data and materials' section, please provide information about where the data supporting your findings can be found. We encourage authors to deposit their datasets in publicly available repositories (where available and appropriate), or to be presented within the manuscript and/or additional supporting files. Please note that identifying/confidential patient data should not be shared. Authors who do not wish to share their data must state that data will not be shared, and provide reasons for this in the manuscript text. For further guidance on how to format this section, please refer to BioMed Central's editorial policies page -

Response: We have provided information about the location of our data that supports our study in the manuscript per the submission requirements on the editorial policies page; see above response.