

Review Form 3

Journal Name:	Journal of Pharmaceutical Research International
Manuscript Number:	Ms_JPRI_121572
Title of the Manuscript:	The Effect of the RMA Designation on Biotechnology Stock Prices, Drug Development Timelines and Outcomes: An Empirical Analysis
Type of the Article	

General guidelines for the Peer Review process:

This journal's peer review policy states that **NO** manuscript should be rejected only on the basis of '**lack of Novelty**', provided the manuscript is scientifically robust and technically sound. To know the complete guidelines for the Peer Review process, reviewers are requested to visit this link:

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Important Policies Regarding Peer Review

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PART 1: Review Comments

Compulsory REVISION comments	Reviewer's comment	Author's Feedback (Please correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
<p>Please write a few sentences regarding the importance of this manuscript for the scientific community. Why do you like (or dislike) this manuscript? A minimum of 3-4 sentences may be required for this part.</p>	<p>From my point of view, it is a very interesting topic and simultaneously it seems that to the best of my knowledge is an important study investigated the impact of the U.S. FDA's Regenerative Medicine Advanced Therapy (RMAT) designation on the valuation and development trajectories of biotech and small pharma companies in cell and gene therapies. Using an event-study approach, share price reactions post-RMAT announcements were analyzed and related to product development outcomes over various windows up to three years. Results revealed an immediate share price boost post-RMAT of approximately 8.11% after 5 days, signaling investor optimism. However, a long-term downward trend emphasized the need for sustainable long-reaching development strategies. Few products reached the market, and around 20% of companies faced significant corporate changes, impacting long-term share prices. Additionally, RMAT products had longer development timelines than those in previous studies. These insights underline RMAT's complex implications, suggesting important considerations for stakeholders and emphasizing the need for continued research and regulatory refinement.</p>	
<p>Is the title of the article suitable? (If not please suggest an alternative title)</p>	<p>Yes</p>	
<p>Is the abstract of the article comprehensive? Do you suggest the addition (or deletion) of some points in this section? Please write your suggestions here.</p>	<p>The abstract must contain the main purpose of the paper, the research method used in the research and the main contributions.</p>	
<p>Are subsections and structure of the manuscript appropriate?</p>	<p>Yes</p>	
<p>Please write a few sentences regarding the scientific correctness of this manuscript. Why do you think that this manuscript is scientifically robust and technically sound? A minimum of 3-4 sentences may be required for this part.</p>	<p>It would be very useful to add in the "Introduction" section the purpose, objectives and hypothesis of the research.</p>	

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<p>Are the references sufficient and recent? If you have suggestions of additional references, please mention them in the review form.</p> <p>-</p>	<p>1. Also, we consider that the literature is not enough and we recommend the authors to refer to other recent works indexed in Web of Science, Scopus, Emerald and Cambridge. We suggest that the authors cite papers indexed in Web of Science Journals, such as:</p> <ol style="list-style-type: none">1. Batrancea L., Batrancea I., Moscviciov A. (2009), The Roots of the World Financial Crisis, Annals of Faculty of Economics, 3(1):57-62.2. Moscviciov, A., Bătrâncea, I., Bătrâncea, M., Bătrâncea, L.M. (2010) Financial Ratio Analysis Used In the IT Enterprises, Annals of the University of Oradea: Economic Science, 19(2):600-603.3. Batrancea LM, Nichita A, Balci MA, Akgüller Ö (2023) Empirical investigation on how wellbeing- related infrastructure shapes economic growth: Evidence from the European Union regions. PLoS ONE 18(4): e0283277. https://doi.org/10.1371/journal.pone.0283277, ISSN:1932-6203.4. Batrancea, L., Batrancea, I., Moscviciov, A. (2009) The analysis of the entity's liquidity—A means of evaluating cash flow, Journal of International Finance and Economics, 9(1):92-98.5. Batrancea, L., Rathnaswamy, M.K. & Batrancea, I. A Panel Data Analysis on Determinants of Economic Growth in Seven Non-BCBS Countries. J Knowl Econ (2021). https://doi.org/10.1007/s13132-021-	
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	<p>00785-y</p> <ol style="list-style-type: none">6. Batrancea LM.(2021) An Econometric Approach on Performance, Assets, and Liabilities in a Sample of Banks from Europe, Israel, United States of America, and Canada. Mathematics. 2021; 9(24):3178. https://doi.org/10.3390/math9243178/.7. Batrancea, L. The Nexus between Financial Performance and Equilibrium: Empirical Evidence on Publicly Traded Companies from the Global Financial Crisis Up to the COVID-19 Pandemic. J. Risk Financial Manag. 2021, 14, 218. https://doi.org/10.3390/jrfm140502188. Batrancea, L. Empirical Evidence Regarding the Impact of Economic Growth and Inflation on Economic Sentiment and Household Consumption. J. Risk Financial Manag. 2021, 14, 336. https://doi.org/10.3390/jrfm140703369. Batrancea, L.; Pop, M.C.; Rathnaswamy, M.M.; Batrancea, I.; Rus, M.-I. An Empirical Investigation on the Transition Process toward a Green Economy. Sustainability 2021, 13, 13151. https://doi.org/10.3390/su13231315110. Batrancea, L.M. (2022) Determinants of Economic Growth across the European Union: A Panel Data Analysis on Small and Medium Enterprises. Sustainability, 14, 4797. https://doi.org/10.3390/su14084797/Accession Number WOS:000786368500001/ ISSN: 2071-1050.11. Batrancea, L.M., Rathnaswamy, M.M., Rus, M.I., Tulai H.(2022) Determinants of Economic Growth for the Last Half of Century: A Panel Data Analysis on 50 Countries. J Knowl Econ, Pp.1-25, https://doi.org/10.1007/s13132-022-00944-9.12. Batrancea, L.M. Determinants of Economic Growth across the European Union: A Panel Data Analysis on Small and Medium Enterprises. Sustainability 2022, 14, 4797. https://doi.org/10.3390/su1408479713. Batrancea, L.M.; Balci, M.A.; Chermezan, L.; Akgüller, Ö.; Masca, E.S.; Gaban, L. Sources of SMEs Financing and Their Impact on Economic Growth across the European Union: Insights from a Panel Data Study Spanning Sixteen Years. Sustainability 2022, 14, 15318. https://doi.org/10.3390/su14221531814. Batrancea, L.M.; Balci, M.A.; Akgüller, Ö.; Gaban, L. What Drives Economic Growth across European Countries? A Multimodal Approach. Mathematics 2022, 10, 3660. https://doi.org/10.3390/math1019366015. Batrancea, L.; Rathnaswamy, M.M.; Batrancea, I. (2021) A Panel Data Analysis of Economic Growth Determinants in 34 African Countries. J. Risk Financial Manag. 14, 260. https://doi.org/10.3390/jrfm14060260 <p>5. We also consider that an important cause that influences GDP is fiscal compliance and therefore even if this variable was not taken into account, the authors should refer to the works published on this topic, namely:</p> <ol style="list-style-type: none">16. Batrancea L.M., Nichita R.A., Batrancea I. (2012), Tax Non-Compliance Behavior in the Light of Tax Law Complexity and the Relationship between Authorities and Taxpayers, Annals of the	
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	<p>Alexandru IoanCuza University-Economics, 59(1), pp.97–106.</p> <p>17. Nichita R.A., Batrancea L.M., (2012), The Implications of Tax Morale on Tax Compliance Behavior, Annals of University of Oradea: Economic Science, 21(1)1, 739–744.</p>	
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	<p>18. Batrancea, L.M., Kudła, J., Błaszczak, B., Kopyt, K. (2022) Differences in tax evasion attitudes between students and entrepreneurs under the slippery slope framework, Journal of Economic Behavior & Organization, Volume 200, Pages 464-482, ISSN 0167-2681, https://doi.org/10.1016/j.jebo.2022.06.017</p> <p>19. Kogler, C., Olsen, J., Kirchler, E., Batrancea, L.M., & Nichita, A. (2022) Perceptions of trust and power are associated with tax compliance: A cross-cultural study, Economic and Political Studies, DOI: 10.1080/20954816.2022.2130501, Print ISSN: 2095-4816 Online ISSN: 2470-4024.</p> <p>20. Batrancea, L. M., Nichita, A., De Agostini, R., Batista Narcizo, F., Forte, D., Mamede, S. D. P. N., Roux-Cesar, A. M., Nedev, B., Vitek, L., Pántya, J., Salamzadeh, A., Nduka, E. K., Kudła, J., Kopyt, M., Pacheco, L., Maldonado, I., Isaga, N., Benk, S., & Budak, T. (2022). A self-employed taxpayer experimental study on trust, power, and tax compliance in eleven countries. Financial Innovation, 8(1), 1-23, https://doi.org/10.1186/s40854-022-00404-y, ISSN:2199-4730</p> <p>21. Batrancea, L.M., Kudła, J., Błaszczak, B., Kopyt, M. (2023) A dataset on declared tax evasion attitudes of students and entrepreneurs from Poland under the slippery slope framework, Data in Brief, 109183, ISSN 2352-3409, https://doi.org/10.1016/j.dib.2023.109183.</p> <p>7. Another important cause that must be mentioned in the paper is the link between GDP, fiscal compliance and shadow economy, as the independent variables fiscal compliance and shadow economy strongly influence GDP. In this sense, I recommend the authors to quote the paper: 22. Batrancea L., Nichita A., Batrancea I., Gaban L. (2018). „The Strength of the Relationship Between Shadow Economy and Corruption: Evidence from a Worldwide Country-Sample”. Social Indicators Research, 138(3), 1119-1143; DOI: 10.1007/s11205-017-1696-z</p>	
<p>Minor REVISION comments</p> <p>Is the language/English quality of the article suitable for scholarly communications?</p>	<p>Yes</p>	
<p>Optional/General comments</p>	<p>The Manuscript needs careful English proofreading because there are some shortcomings. For instance, the article “the” is sometimes missing in front of nouns, the message in some paragraphs is not clear enough.</p>	

PART 2:

	<p>Reviewer’s comment</p>	<p>Author’s comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)</p>
<p>Are there ethical issues in this manuscript?</p>	<p><i>(If yes, Kindly please write down the ethical issues here in details)</i></p>	

Reviewer Details:

<p>Name:</p>	<p>Batrancea Larissa Margareta</p>
<p>Department, University & Country</p>	<p>Babes-Bolyai University, Romania</p>