ReviewForm 1.7

JournalName:	**JournalofComplementaryandAlternativeMedicalResearch**
ManuscriptNumber:	**Ms_JOCAMR_119490**
Titleof theManuscript:	**AlinPost-MarketSurveillanceofMedicalDevices**
Typeof the Article	

ReviewForm 1.7

PART1:ReviewComments

	Reviewer'scomment	**Author'scomment***(ifagreedwithreviewer,correct themanuscriptandhighlightthatpartinthe manuscript.Itis mandatorythatauthorsshouldwrite his/herfeedbackhere)*
	Myanalysis: Strengths: 1. Relevance: Thepaperaddressesatimelyand important topic in healthcareand regulatoryscience. As medical devices becomemore complexand abundant, efficient post- market surveillanceis crucial. 2. Comprehensive scope:The abstract outlines multiple applications of AIin PMS, includingsignal detection, risk assessment, and regulatorycompliance, providingabroad overview ofthe field. 3. Balanced perspective:Thepaper acknowledgesboth thepotential benefits and challenges of AIin PMS, demonstrating anuanced approach to thetopic. 4. Real-world focus: Theemphasis on real-worldevidenceand data sources (patient outcomes, adverse eventreports, EHRs) highlights the practical applications of AI in PMS. 5. Regulatoryimplications: The paperconsiders theimpact of AIonregulatoryoversight, which is crucial for thepractical implementation of thesetechnologies. Limitations and areas forimprovement: 1.Lack of specific methodologies: Theabstract doesn't mention specific AItechniques or algorithms used in PMS, which could providemore concrete insights into the field's current state. 2.Limited discussion ofvalidation: Whilethe conclusion mentions theneed forvalidation, more emphasis on how AImodelsarevalidated for usein PMSwould strengthen thepaper. 3. Absenceof casestudies:Includingspecific examples or casestudies of AIapplications in PMScould enhancethe paper's practical relevance. 4. Data qualityconsiderations: The abstract doesn't address thecritical issue ofdata quality in AI-driven PMSsystems, which is essential forreliable results. 5.Interoperability: Thepaper could benefit from discussinginteroperabilitychallenges between different AIsystems and data sources inPMS. 6. Regulatoryframework: Moredetailed discussion on how existingregulatoryframeworks areadaptingto incorporate AIin PMSwould bevaluable. 7. Comparative analysis:A comparison of AI-driven PMSwith traditionalmethods could better illustrate the advantages andlimitations of AIapproaches. Suggestions for futureresearch: 1.Investigate specificAI algorithms and their performancein different PMStasks. 2. Explorethe integrationof AI-driven PMSwith other healthcaretechnologies and systems. 3. Conduct longitudinal studies to assess thelong-term impact of AIon PMSeffectiveness and patient outcomes. 4. Examinethe cost-effectiveness of implementing AIin PMScompared totraditional methods. 5. Develop standardized protocols forvalidating AImodels in PMSapplications. 6.Investigate methods to enhancethe interpretabilityof AI algorithms in PMSto address transparencyconcerns. Overall, this paperappears to provide avaluableoverview ofAIapplications in post- market surveillanceof medical devices.It addresses keybenefits and challenges, settingthe stageformorein-depth research in this rapidlyevolvingfield. However, morespecific details on methodologies, validation processes,andreal-world implementations would furtherstrengthen its scientific contribution.	

ReviewForm 1.7

CompulsoryREVISIONcomments **1. Isthemanuscript important forscientific community?** (Please writefewsentenceson this manuscript) **2. Isthetitleofthearticlesuitable?** (Ifnotpleasesuggest analternative title) **3. Isthe abstract ofthearticlecomprehensive?** **4. Are subsectionsandstructureof themanuscript appropriate?** **5. Doyou thinkthemanuscript isscientificallycorrect?** **6. Are the references sufficientandrecent?If you have suggestionofadditionalreferences,please mentioninthe reviewform.** **(Apartfromabove mentioned6 points, reviewersare freetoprovide additionalsuggestions/comments)**	**Somewhat** **yes** **Somewhat** **Somewhat** **Somewhat** **Somewhat** **Myanalysis:** **Strengths:** **1.Relevance:Thepaperaddressesatimelyandimportanttopicinhealthcareand regulatoryscience.Asmedicaldevicesbecomemorecomplexandabundant, efficientpost-marketsurveillanceis crucial.** **2.Comprehensivescope:TheabstractoutlinesmultipleapplicationsofAIin PMS, includingsignaldetection,riskassessment,andregulatorycompliance,providinga broadoverviewofthefield.** **3.Balancedperspective:Thepaperacknowledgesboththepotentialbenefitsand challengesofAIin PMS,demonstratinganuancedapproachtothetopic.** **4.Real-worldfocus:Theemphasison real-worldevidenceanddatasources(patient outcomes,adverseeventreports,EHRs)highlightsthepracticalapplicationsofAIin PMS.** **5.Regulatoryimplications:Thepaperconsiderstheimpactof AI on regulatory oversight,whichiscrucialforthepracticalimplementationofthesetechnologies.** **Limitationsandareasforimprovement:** **1.Lackofspecificmethodologies:TheabstractdoesntmentionspecificAI techniquesor algorithmsusedinPMS,whichcouldprovidemoreconcreteinsights intothefield'scurrentstate.** **2.Limiteddiscussionofvalidation:Whiletheconclusionmentionstheneedfor validation,moreemphasisonhowAImodelsarevalidatedforusein PMSwould strengthenthepaper.** **3.Absenceofcasestudies:IncludingspecificexamplesorcasestudiesofAI applicationsinPMScouldenhancethepaper'spracticalrelevance.** **4.Dataqualityconsiderations:Theabstractdoesn'taddressthecriticalissueofdata qualityinAI-drivenPMSsystems,whichisessentialforreliableresults.** **5.Interoperability:Thepapercouldbenefitfromdiscussinginteroperability challengesbetweendifferent AI systemsanddatasourcesin PMS.** **6.Regulatoryframework:Moredetaileddiscussiononhowexistingregulatory frameworksareadaptingtoincorporateAI in PMSwouldbevaluable.** **7.Comparativeanalysis:AcomparisonofAI-drivenPMSwithtraditionalmethods couldbetterillustratetheadvantagesandlimitationsofAIapproaches.** **Suggestionsforfutureresearch:** **1.InvestigatespecificAI algorithmsandtheirperformanceindifferentPMStasks.** **2.Exploretheintegrationof AI-drivenPMSwithotherhealthcaretechnologiesand systems.** **3.Conductlongitudinalstudiestoassessthelong-termimpactofAIonPMS effectivenessandpatientoutcomes.** **4.Examinethecost-effectivenessofimplementingAIinPMScomparedtotraditional**	

	methods. 5.DevelopstandardizedprotocolsforvalidatingAImodelsin PMSapplications. 6.InvestigatemethodstoenhancetheinterpretabilityofAI algorithmsin PMSto addresstransparencyconcerns. Overall,thispaperappearstoprovideavaluableoverviewofAI applicationsinpost-market surveillanceofmedicaldevices.Itaddresseskeybenefitsandchallenges,settingthestage formorein-depthresearchinthisrapidlyevolvingfield.However,morespecificdetailson methodologies,validationprocesses,andreal-worldimplementationswouldfurther strengthenits scientificcontribution.	

ReviewForm 1.7

MinorREVISIONcomments **1. Islanguage/Englishqualityofthe articlesuitableforscholarly communications?**	Somewhat	
Optional/Generalcomments	Myanalysis: Strengths: 1.Relevance:Thepaperaddressesatimelyandimportanttopic inhealthcareandregulatory science.Asmedicaldevicesbecomemorecomplexandabundant,efficientpost-market surveillanceis crucial. 2.Comprehensivescope:Theabstractoutlinesmultipleapplicationsof AI in PMS,includingsignal detection,risk assessment,andregulatorycompliance,providinga broadoverviewof thefield. 3.Balancedperspective:Thepaperacknowledgesboththepotentialbenefitsandchallengesof AI in PMS,demonstratinganuancedapproachtothetopic. 4.Real-worldfocus:Theemphasisonreal-worldevidenceanddatasources(patientoutcomes, adverseeventreports,EHRs)highlightsthepracticalapplicationsof AIinPMS. 5.Regulatoryimplications:Thepaperconsiderstheimpactof AI onregulatoryoversight,whichis crucialforthepracticalimplementationof thesetechnologies. Limitationsandareasforimprovement: 1.Lackofspecificmethodologies:Theabstractdoesn'tmentionspecificAItechniquesor algorithmsusedin PMS,whichcouldprovidemoreconcreteinsightsintothefield'scurrentstate. 2.Limiteddiscussionof validation:Whiletheconclusionmentionstheneedforvalidation,more emphasisonhowAI modelsarevalidatedforuse in PMSwouldstrengthenthepaper. 3.Absenceof casestudies:Includingspecificexamplesorcasestudiesof AIapplicationsin PMS couldenhancethepaper'spracticalrelevance. 4.Dataqualityconsiderations:Theabstractdoesn'taddressthecriticalissueofdataqualityinAI-drivenPMSsystems,whichis essentialforreliableresults. 5.Interoperability:Thepapercouldbenefitfrom discussinginteroperabilitychallengesbetween differentAIsystemsanddatasourcesin PMS. 6.Regulatoryframework:Moredetaileddiscussiononhowexistingregulatoryframeworksare adaptingto incorporateAI inPMSwouldbe valuable. 7.Comparativeanalysis:A comparisonof AI-drivenPMSwithtraditionalmethodscouldbetter illustratetheadvantagesandlimitationsof AIapproaches. Suggestionsforfutureresearch: 1.InvestigatespecificAIalgorithmsandtheirperformanceindifferentPMStasks. 2.Exploretheintegrationof AI-drivenPMSwithotherhealthcaretechnologiesandsystems. 3.Conductlongitudinalstudiestoassessthe long-term impactof AIonPMSeffectivenessand patientoutcomes. 4.Examinethecost-effectivenessof implementingAI inPMScomparedtotraditionalmethods. 5.DevelopstandardizedprotocolsforvalidatingAImodelsin PMSapplications. 6.Investigatemethodsto enhancethe interpretabilityof AIalgorithmsinPMStoaddress transparencyconcerns. Overall,thispaperappearstoprovideavaluableoverviewof AIapplicationsinpost-market surveillanceofmedicaldevices.Itaddresseskeybenefitsandchallenges,settingthestagefor morein-depthresearchinthisrapidlyevolvingfield.However,morespecificdetailson methodologies,validationprocesses,andreal-worldimplementationswouldfurtherstrengthenits scientificcontribution.	

	Reviewer'scomment Myanalysis: Strengths: 1. Relevance: Thepaperaddressesatimelyand important topic in healthcareand regulatoryscience. As medical devices becomemore complexand abundant, efficient post-market surveillanceis crucial. 2. Comprehensive scope:The abstract outlines multiple applications of AIin PMS, includingsignal detection, risk assessment, and regulatorycompliance, providinga broad overview ofthefield. 3. Balanced perspective:Thepaper acknowledgesboth thepotential benefits and challenges of AIin PMS, demonstrating anuanced approach to thetopic. 4. Real-world focus: Theemphasis on real-worldevidenceand data sources (patient outcomes, adverse eventreports, EHRs) highlights the practical applications of AIin PMS. 5. Regulatoryimplications: The paperconsiders theimpact of AIonregulatory oversight, which is crucial forthe practical implementation ofthesetechnologies. Limitations and areas forimprovement: 1.Lack of specific methodologies: Theabstract doesn't mention specific AItechniques or algorithms used in PMS, which could providemore concrete insights into the field's current state. 2.Limited discussion ofvalidation: Whilethe conclusion mentionsthe need for validation, more emphasis on how AImodels arevalidated foruse in PMSwould strengthen the paper. 3. Absenceof casestudies:Includingspecific examples or casestudies of AI applications in PMScould enhancethe paper's practical relevance. 4. Data qualityconsiderations: The abstract doesn't address thecritical issue ofdata qualityin AI-driven PMSsystems, which is essential for reliable results. 5.Interoperability: Thepaper could benefit from discussinginteroperabilitychallenges between different AIsystems and data sources inPMS. 6. Regulatoryframework: Moredetailed discussion on how existingregulatory frameworks are adapting to incorporate AIin PMSwould bevaluable. 7. Comparative analysis:A comparison of AI-driven PMSwithtraditionalmethods could betterillustrate theadvantagesand limitations of AIapproaches. Suggestions for futureresearch: 1.Investigate specificAI algorithms and their performancein different PMStasks. 2. Explorethe integrationof AI-driven PMS with otherhealthcaretechnologies and systems. 3. Conduct longitudinal studies to assess thelong-term impact of AIon PMS	**Author'scomment***(ifagreedwithreviewer,correctthe manuscriptandhighlightthatpart in themanuscript.Itis mandatorythatauthorsshouldwritehis/herfeedbackhere)*

	effectiveness and patientoutcomes. 4. Examinethe cost-effectiveness of implementing AIin PMScompared totraditional methods. 5. Develop standardized protocols forvalidating AImodels in PMSapplications. 6.Investigate methods to enhancethe interpretabilityof AI algorithms in PMSto address transparencyconcerns. Overall, this paperappears to provide avaluableoverview ofAIapplications in post- market surveillanceof medical devices.It addresses keybenefits and challenges, settingthe stageformorein-depth research in thisrapidlyevolving field. However, morespecific details onmethodologies, validation processes,and real-world implementations would furtherstrengthen its scientific contribution.	

PART 2:

	Reviewer's comment	**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)*
Are there ethical issues in this manuscript?	*(If yes, Kindly please write down the ethical issues here in details)*	

Reviewer Details:

Name:	**Mohammed Aboud Kadhim**
Department, University & Country	**Middle Technical University, Iraq**