April 13, 2023 @ 11:00 am Pacific

Why did the FDA reject your rationale for no human factors testing?

IVD v3.0 FDA eSTAR

Performance Testing

Analytical Performance

Did you perform Precision (Repeatability/Reproducibility) Study?		?
Did you perform Linearity Study?		?
Did you perform Analytical		?
Do you have Assay Measu		?
Did you perform Analytical		?
Did you perform Assay Cut		?
Do you have Traceability in		?
Do you have Stability information to include in this submission?		?
Do you have other Analytical Performance Supportive Data to include in this submission?		?

Warning: JavaScript Window - Section Content

Contains analytical performance information that may be important to the submission but does not fit in any of the other headings of Analytical Performance.

NOTE: Usability/Human Factors Studies specifically assessing the instructions and/or device design in terms of impact of human behaviour, abilities, limitations, and other characteristics on the ability of the device to perform as intended should be included here. However, Human Factors Studies that include patients or performed as part of a clinical study should be included in the Clinical Studies section under Clinical Supportive Data question below.

OK

Where do you attach the data?

Do you have other Analytical Performance Supportive Data to include in this submission?	Yes ?
Provide a brief summary of the other Analytical Performance Supportive Data you included in this submission.	
Add Attachment	Please attach documentation that includes details of other Analytical Performance Supportive Data obtained with your device.

nIVD v3.0 FDA eSTAR

Performance Testing

Was Bench Testing used in order to support this submission?	Yes
Was Animal Testing used in order to support this submission?	
Was Clinical Testing used in order to support this submission?	

Bench Testing ?

Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.

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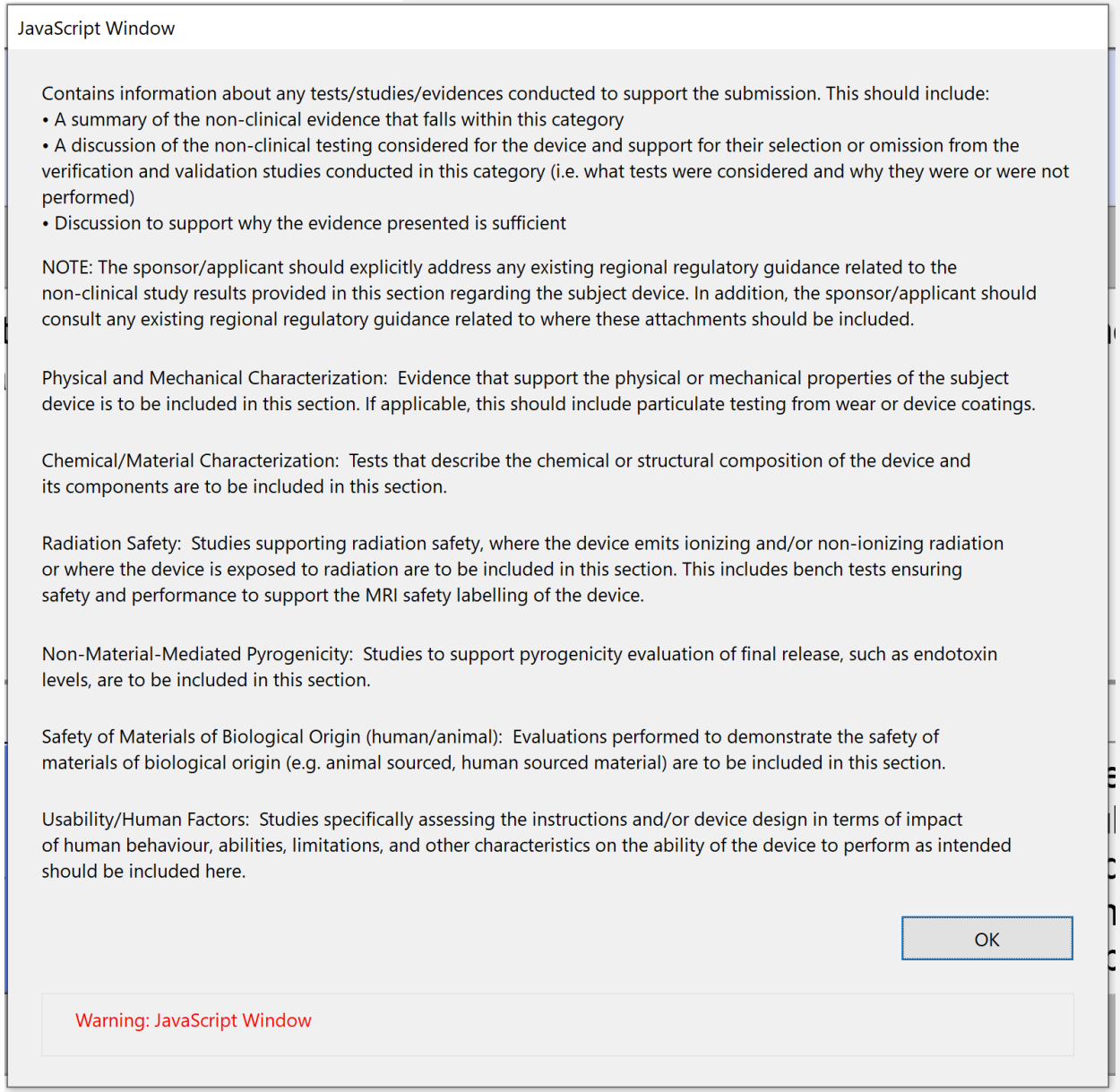
Add Attachment	Please attach documentation that includes details of the bench testing performed with your device (test report, characterization, etc). A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission.	?

Java Script Box



What does Bing say?

1. The documentation is incomplete or inaccurate.
2. The documentation does not demonstrate that the device is substantially equivalent to a previously cleared device.
3. The documentation does not provide sufficient information about the device's intended use and technical characteristics.
4. The documentation does not provide sufficient information about the device's safety and effectiveness.
5. The documentation does not provide sufficient information about the device's design validation and verification activities.
6. The documentation does not provide sufficient information about the device's risk analysis activities.
7. The documentation does not provide sufficient information about the device's usability engineering activities.
8. The documentation does not provide sufficient information about the device's labeling and instructions for use.
9. The documentation does not provide sufficient information about the device's software validation and verification activities.
10. The documentation does not provide sufficient information about the device's clinical evaluation activities.

Top 10 mistakes

1. Following IEC 62366-1, because it is “recognized”
2. Following 2016 Guidance, because it is “Final”
3. Following ISO 14971:2019 for your usability risk analysis
4. No rationale for the sample size
5. Conducting your study outside the USA
6. No search of MAUDE database
7. No formative testing
8. No URRA with critical tasks identified
9. Changing the IFU after the summative testing
10. No script for moderators

https://sheoli.art

IEC 62366-1 & IEC 60601-1-6 Recognition

IEC 62366-1 Amd.1 Ed. 1.0 b:2020

Amendment 1 - Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices

IEC 60601-1-6 Ed. 3.2 b:2020

Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability

FDA 2016 Guidance on Human Factors

Contains Nonbinding Recommendations

Applying Human Factors and Usability Engineering to Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on: February 3, 2016

As of April 3, 2016, this document supersedes "Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management" issued July 18, 2000.

The draft of this document was issued on June 21, 2011.

Contains Nonbinding Recommendations

Draft – Not for Implementation

Content of Human Factors Information in Medical Device Marketing Submissions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on December 9, 2022.

ISO 14971:2019 Standard for Risk Management

Process Step	Potential Failure Mode	Potential Failure Effect	SEV[1]	Potential Causes	OCC[2]	Current Process Controls	DET[3]	RPN[4]	Action Recommended
What is the step?	In what ways can the step go wrong?	What is the impact on the customer if the failure mode is not prevented or corrected?	How severe is the effect on the customer?	What causes the step to go wrong (i.e., how could the failure mode occur)?	How frequently is the cause likely to occur?	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	How probable is detection of the failure mode or its cause?	Risk priority number calculated as SEV x OCC x DET	What are the actions for reducing the occurrence of the cause or for improving its detection? Provide actions on all high RPNs and on severity ratings of 9 or 10.
ATM Pin Authentication	Unauthorized access	• Unauthorized cash withdrawal • Very dissatisfied customer	8	Lost or stolen ATM card	3	Block ATM card after three failed authentication attempts	3	72	
	Authentication failure	Annoyed customer	3	Network failure	5	Install load balancer to distribute workload across network links	5	75	
Dispense Cash	Cash not disbursed	Dissatisfied customer	7	ATM out of cash	7	Internal alert of low cash in ATM	4	196	Increase minimum cash threshold limit of heavily used ATMs to prevent out-of-cash instances
	Account debited but no cash disbursed	Very dissatisfied customer	8	• Transaction failure • Network issue	3	Install load balancer to distribute workload across network links	4	96	
	Extra cash dispensed	Bank loses money	8	• Bills stuck to each other • Bills stacked incorrectly	2	Verification while loading cash in ATM	3	48	

1. **Severity**: Severity of impact of failure event. It is scored on a scale of 1 to 10. A high score is assigned to high-impact events while a low score is assigned to low-impact events.
2. **Occurrence**: Frequency of occurrence of failure event. It is scored on a scale of 1 to 10. A high score is assigned to frequently occurring events while events with low occurrence are assigned a low score.
3. **Detection**: Ability of process control to detect the occurrence of failure events. It is scored on a scale of 1 to 10. A failure event that can be easily detected by the process control is assigned a low score while a high score is assigned to an inconspicuous event.
4. **Risk priority number**: The overall risk score of an event. It is calculated by multiplying the scores for severity, occurrence and detection. An event with a high RPN demands immediate attention while events with lower RPNs are less risky.

Sample Size Rationale

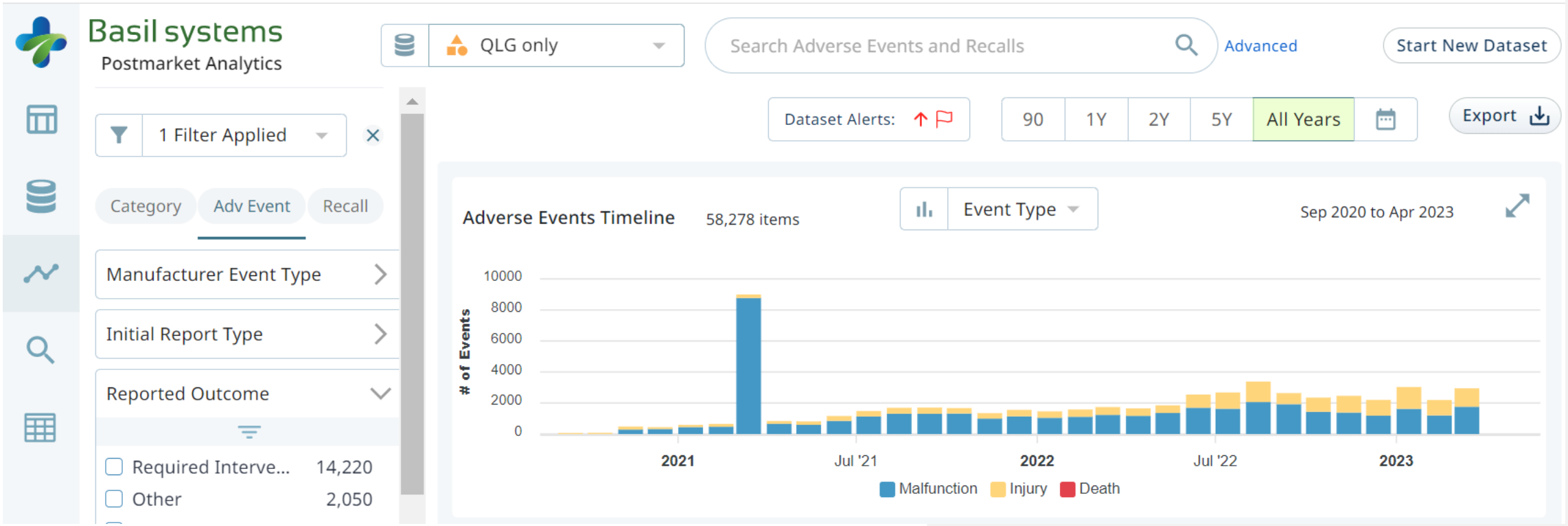
Table B-1. Percentage of Total Known Usability Problems Found in 100 Analysis Samples (Faulkner, 2003).

No. users	Min. % Found	Mean % Found	*SD*	*SE*
5	55	85.55	9.2957	.9295
10	82	94.69	3.2187	.3218
15	90	97.05	2.1207	.2121
20	95	98.4	1.6080	.1608
30	97	99.0	1.1343	.1051

OUS Studies

For the results of the human factors validation testing to demonstrate safe and effective use by users in the United States, the participants in the testing should reside in the US. Studies performed in other countries or with non-US residents may be affected (positively or negatively) by different clinical practices that exist in other countries, different units of measure used, language differences that change the way labeling and training are understood, etc. Exceptions to this policy will be considered on a case-by-case basis and will be based on a sound rationale that considers the relevant differences from conditions in the US. In addition to the user interface of the device, the labeling and training should correspond exactly to that which would be used for the device if marketed in the US.

MAUDE Database



2 Records Categorized as Human Factors Issues in March 2023

Formative testing

- Improvement of user experience (UX)
- Eliminate and simplify difficult tasks
- Identifying unexpected use errors
- Option control risk analysis for the user interface (UI)
- Testing your directions for use
- Pre-test your summative protocol

URRA & Critical Tasks

Table 2. Example tabular format for the use-related risk analysis

Use-related risk analysis Task #	User Task	Possible use error(s)	Potential hazards and clinical harm	Severity of harm	Critical Task (Y/N)	Risk Mitigation Measure(s)[25]	Validation method for effectiveness of risk mitigation measure[26]
Task #1							
Task #2							

IFU Changes

- Version must be specified in the summative testing protocol
- If multiple versions are used during summative testing, the changes must be justified
- If the submission has a different version, the changes must be justified
- The changes need to be identified using “redline” feature
- Eliminate the formatting of the IFU and have a simple Word document

Script for Moderators

- The moderator will instruct the subject to open the box and assemble the device according to the directions for use.

VS

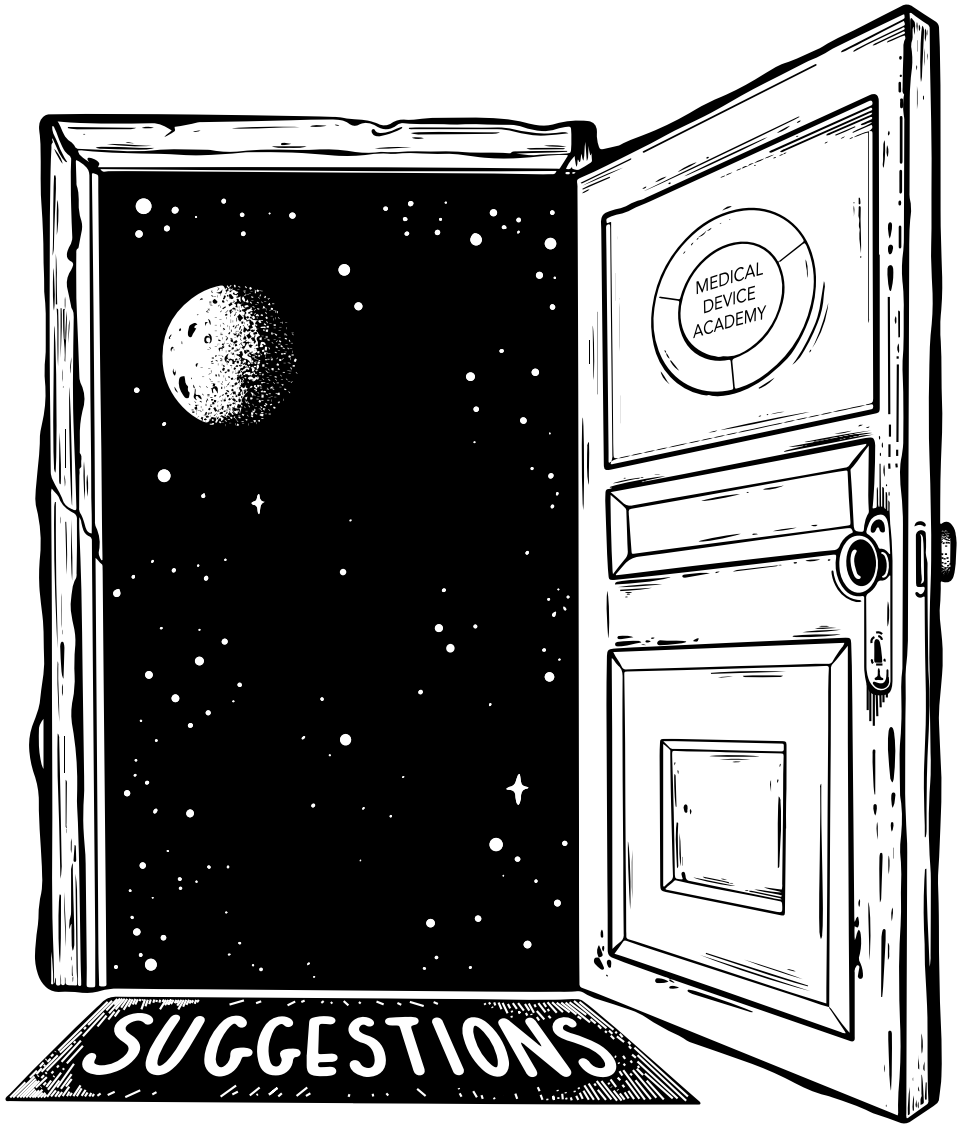
- “Please open the box and assemble the device according to the directions.”

OR

- “Please open the box and assemble the device according to the directions, but make sure you follow the directions in the order specified on page 3.”

What does OpenAI say? (powered by GPT-4)

1. Insufficient human factors testing: The submitted documentation may not include enough evidence of robust human factors testing or may lack proper testing methodologies. – Too Vague
2. Incomplete risk analysis: The FDA requires a thorough risk analysis to identify and mitigate potential use-related hazards. Inadequate or incomplete risk analysis can lead to a rejected submission. – Too Vague
3. Poorly defined user population: The documentation may not clearly define the intended user population, leading to concerns about the device's safety and effectiveness for all potential users.
4. Inadequate validation testing: The submission may lack sufficient evidence of validation testing, which is crucial for demonstrating that a device can be used safely and effectively by the intended users. – This is related to traceability found below.
5. Inadequate usability testing: The submission may not have enough information on usability testing or may lack a clear description of the methodologies used to test the device's usability. – Too Vague
6. Missing or incomplete training materials: The FDA requires comprehensive training materials to ensure that users can safely and effectively operate the device. Missing or incomplete materials can lead to a rejected submission. – This goes somewhat beyond the requirement to provide the version of the IFU that was used and a moderator script.
7. Insufficient mitigation measures: The documentation may not adequately describe the steps taken to mitigate potential use-related hazards or may not provide evidence that these measures are effective. – This is related to traceability found below.
8. Lack of traceability: The submission may lack a clear link between the human factors documentation, the risk analysis, and the device's design, making it difficult for the FDA to assess the device's safety and effectiveness.
9. Failure to address known issues: The submission may not address previously identified issues or concerns raised by the FDA, which can result in a rejected submission.
10. Inadequate or unclear documentation: The human factors documentation may be poorly organized, lack clarity, or contain inconsistencies, making it difficult for the FDA to assess the device's safety and effectiveness. – Too Vague



Suggestions for our next Webinar or 10x 2024?

https://medicaldeviceacademy.com/suggestion-box/

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