**## Task**

**1. Please Provide feedback on the requirements that the Product Owner has provided for your review.**

## Product Requirements

1. When a users adds CXR JPEGs to the Web Demo the upload payload shall contain the following content from the file:

\* accessionNumber

\* description

\* patientAge

\* patientId

\* studyInstanceUid

\* The base64 encoded content of the image

**Feedback** – This requirement is missing the Series ID, as per the DICOM standard, which is necessary to handle a series of images being uploaded. It also lacks guidance on how all the metadata should align with the series of images

2. When a user adds CXR DICOMs to the Web Demo the upload payload shall contain the following content:

\* accessionNumber matches the contents of DICOM field (0008,0050)

\* description matches the contents of DICOM field (0008,1030)

\* patientAge matches the contents of DICOM field (0008,1030)

\* patientId matches the contents of DICOM field (0010,1010)

\* studyInstanceUid matches the contents of DICOM field (0020,000D)

\* The base64 encoded content of the image of the PixelData DICOM field (7FE0,0010)

**Feedback** – Series Instance ID (0020, 000E) to be added to handle the group of images together as part of the same series within the study

3. The Web Demo shall poll the Backend until the study results are ready

\* This is indicated by the status being COMPLETED

**Feedback** – This requirement should specify that the system is polling for the status of the study, and it should not only check for "COMPLETED" but also for "PENDING" and "ERROR" statuses. This ensures that the system can handle different stages of study processing (e.g., still being processed, completed, or failed) and respond appropriately.

4. The Web Demo shall display the AI results to the user when ready

\* This shall include the list of findings detected

\* Any findings that have a segmentation, shall have an icon indicating this

**Feedback** – This requirement looks vague and looks like user requirement. This should specify the format of the AI findings (whether it will be highlighted in the image or a list of findings as text) and also criticality of the findings (normal, abnormal and critical).

**2. Using the FDA Guidance for software classification (See [guidance](https://www.fda.gov/media/73065/download) document here pages 4 to 8), what software level of concern would you classify the Annalise Web Demo and why?**

**Answer -** The Annalise Web Demo would likely be classified as a Class II (moderate level of concern) medical device by the FDA regulation. This classification is appropriate because the software assists in interpreting medical images (CXR) using AI, which can aid in diagnosing conditions. While it does not directly provide a diagnosis, the results influence clinical decision-making, which could impact patient safety. As a result, it will fall into moderate level of concern to ensure its accuracy and effectiveness in a clinical setting.

**3. During Verification testing of the Annalise Web Demo, a defect was found around displaying the age in the incorrect format. The aged is displayed as "07/15/98" instead of "15-07-1998". You are assigned to investigate the root cause of the defect, please write down your process of determining the root cause.**

**Answer -**

1. Create a defect ID
2. Gather a field information – more information of this issue from the field service or clinical specialist
3. Bring in the CRB or CFT team – to classify and review the impact of this defect
4. Try to recreate the issue – to find the issue at the formatting or configuration
5. Find the impact area – Check for the issues at UI or date and system format or configuration
6. Inspect the system or code – examine the code which handles the date format.
7. Fix the issue - implement the correct logic for date format
8. Retest the fix - After applying the fix, retest the system to ensure that the date is now displayed in the correct format.
9. Document the root cause –

Root Cause: The root cause of the defect was likely due to a mismatch in date formatting between the backend and frontend, potentially influenced by locale settings or incorrect date handling in the code.

Solution: Standardize the date format across the system (both backend and frontend) and ensure proper handling of the display format.

1. Close the defect.

**4. For the defect described in question 3, would you propose the defect to be deferred for the current release? Please provide justification for you answer.**

**Answer –** I would not recommend deferring this defect for the current release. While the issue with the date format may seem minor and no impact to patient safety, it affects the clarity and accuracy of patient information. Inconsistent data presentation, even in small details like the date format, can harm the system’s readability and accuracy. As medical software, it is essential to maintain high standards of consistency and accuracy. Any deviation from the expected format can lead to confusion or errors in clinical workflows. Correctly displaying patient details, including age, is crucial in healthcare settings.

**5. If Annalise was to make the Web Demo app available for clinical use, what are some of the major safety risks that should be considered and why?**

**Answer –**

**Per ISO 14971, the hazards involved in the Annalise wed demo app are listed below**

**. Hazard**

1. Delay in Diagnosis – The results are not clear or missing information to interpret and this could lead to delay in diagnosis, incorrect image format
2. wrong Diagnosis – AI inaccuracy or software malfunction leads to false positive or negative result, misalignment of patient metadata to the image, poor quality of images
3. System unavailability – System unavailable due to application crash or loss of display
4. Loss of data – Loss of clinical data due to data corruption or user deletes the file unknowingly
5. Security breach (Data loss)- Inadequate data security measures could lead to unauthorized access, theft, or leakage of sensitive patient information.
6. Delay in Alerts – Delay in sending alerts of the risks or limitations of processing to the user due to software bugs or error
7. No Alerts – No feedback of the risks or limitations of processing to the user due to software malfunction
8. Delay in display of Poll status – The poll status id delayed to software malfunction
9. No display of poll status – There is a communication issue of poll status due to software malfunction
10. Incorrect display of poll status - Incorrect display of poll status due to software bugs, error or UI issues