

Sanofi-Aventis Inc.

Smart Error Detector

User Manual

Version 1.0.0

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The wet-ink signatures could not be affixed as associates do not have access to a Cognizant printer and scanner due to the COVID-19 WFH scenario. Hence, approval through email has been considered as an interim approach.

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1.0 Preface

1.1 About the Manual

Welcome to the 'Smart Error Detector' User's Manual. This manual provides a complete reference for the functions and features available in the Smart Error Detector tool.

1.1.1 Audience

This tool is designed for the Cognizant associates. The users must have a clear understanding of Life-Sciences/ Pharmacovigilance process. And it is expected that they will have subject matter expertise on Quality Check process.

1.1.2 Conventions

All the users need to be in Cognizant environment while accessing this tool. It is suggested to open the app from Google Chrome browser to get a better user experience. User's browser should allow pop-up and JavaScript should be enabled in the browser settings.

2.0 Introduction

Smart Error Detector tool will assist the users to perform the narrative quality check in an efficient manner. This tool identifies and highlight different oversight, typo/ cleaning, abbreviation, chronology, etc. errors in the narrative text and provides suggestion for those errors wherever applicable.

3.0 Getting Started

3.1 Logging On

User can login to a Cognizant system using Cognizant credentials. User can then access the tool within Cognizant environment. While accessing this tool via Cognizant RAVPN, user needs to connect to "SANOFI_AVENTIS" RAVPN profile (Gateway: Mumbai, Pune, Chennai, Hyderabad, Kolkata) with their Cognizant credentials. User will have to add "10.127.*;" in the proxy exception list if the proxy server is turned on within user's system proxy settings.

3.2 Exit System

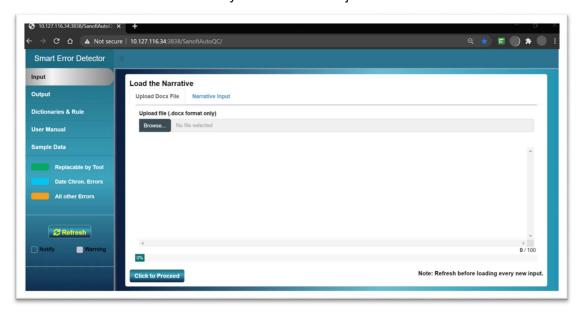
User needs to refresh the tool after processing the narrative. Follow the detailed guideline given in the following section. User can close the tool link to exit.



4.0 Standard Operating Procedure

4.1 Step 1: Open App

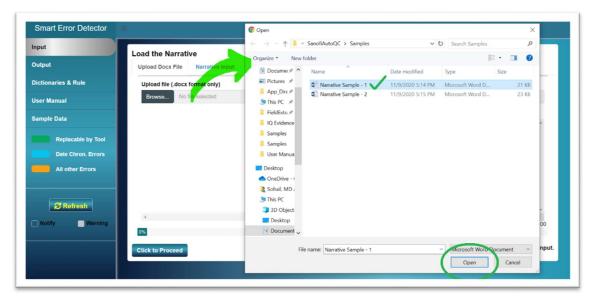
Open the specified app link from browser. It will display the landing page (Input tab) of the "Smart Error Detector" tool. User may zoom in/out to adjust the tool's screen.



4.2 Step 2: Load Narrative

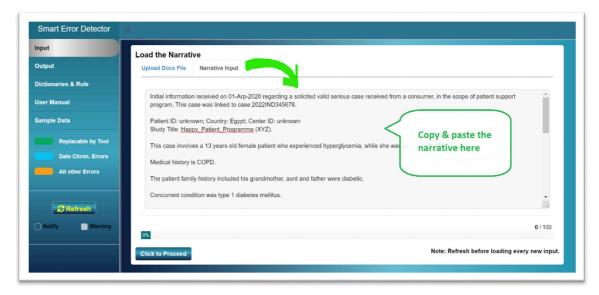
Upload the narrative into the tool:

1. <u>Browse and select one Narrative file</u> ('.docx' format only) and then click on "Open" button to upload the narrative. File drag-and-drop will also work here.



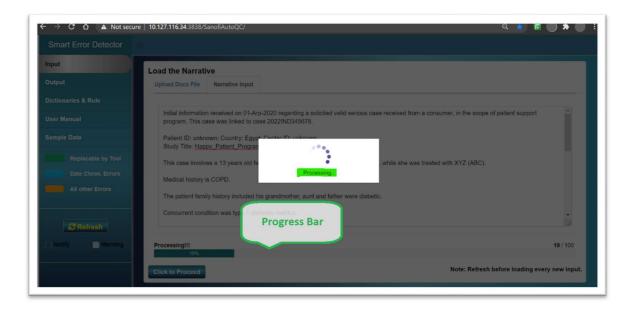


2. OR, <u>Copy-paste the narrative</u> directly in the "Narrative Input" panel. Once the narrative is pasted, it can NOT be edited here.



4.3 Step 3: Processing

Now click on "Click to Proceed" button and wait till the progress bar reaches 100%, i.e. till the processing finishes.



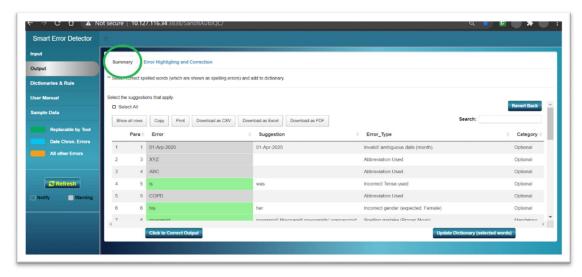


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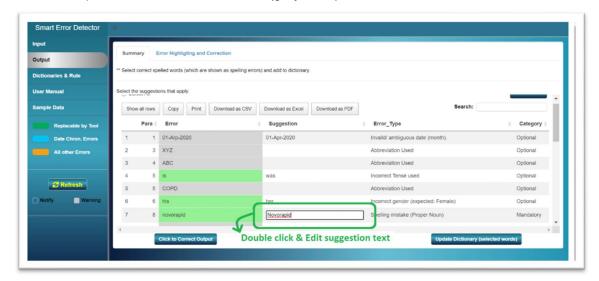
4.4 Step 4: Error Summary Table

Once the processing is completed, tool will redirect to Summary panel of Output tab. This panel contains an <u>Error Summary table</u>. Columns of this table refers to error paragraph no., error word/ phrase, error suggestion (if any), error description, and error category.



4.5 Step 5: Edit Suggestions

User can <u>edit the suggestion of green-colored errors</u> by double clicking on that suggestion. Press 'Enter' or click anywhere outside to save that suggestion. A warning pop-up will appear if user attempts to edit <u>non-editable errors (gray color)</u>.

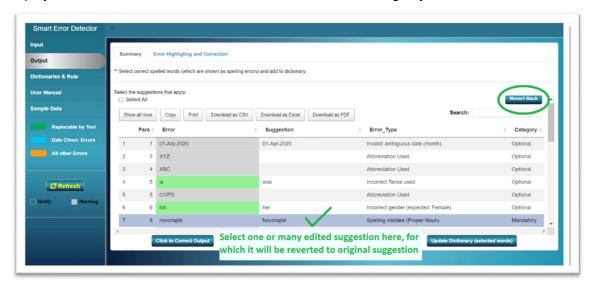




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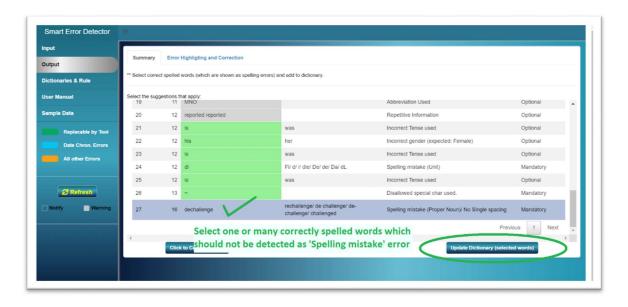
4.6 Step 6: Revert edited Suggestions

User can <u>select one or more rows</u> from the table, then <u>click on the 'Revert Back'</u> button, to revert the edited suggestions back to tool's original suggestion. A warning pop will be displayed if user clicks on "Revert Back" button without selecting any row.



4.7 Step 7: Update Dictionary

User can <u>select one or many rows</u> from the table and <u>click on the 'Update Dictionary'</u> button to update dictionary with correct words. Once these words are validated and added into tool's dictionary, they will not be highlighted as 'spelling mistake' error in future. **Note**: Update dictionary is enabled only for 'Spelling mistake' error type. By this functionality, only the error word will be added into dictionary, not the suggestion.



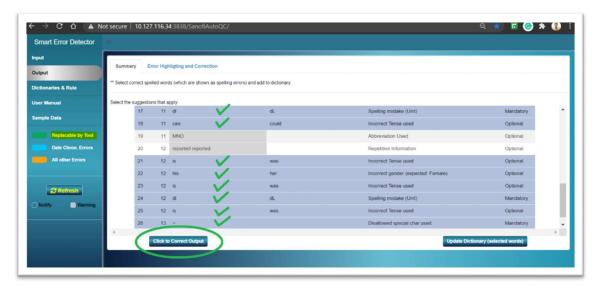


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Step 8: Narrative Correction by Tool

Now select zero or more rows from the Error Summary Table and click on "Click to Correct Output" button to correct the errors by its suggestions, for these selected error rows. Tool will then redirect to next panel "Error Highlighting and Correction". User may click on "Select All" button (located at top of the table), to select all rows at once.

Note: If multiple suggestions are given, by default, the first one will be used for correction by tool. User may edit such suggestions if they want, especially when correct suggestion is not at the first place. Tool can correct the errors which are in green color in the error summary table. Other errors will have to be corrected by user in the next panel.

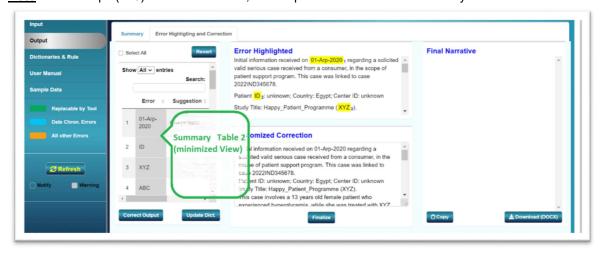


4.9 Step 9: Error Highlighting & Correction

"Error Highlighting and Correction" is the most important screen of the tool. It's the 2nd panel of Output tab. There are four key components in this panel:

- 1. Summary Table 2 (minimized view): replica of error summary shown in "Summary" panel.
- Error Highlighting: All the errors will be highlighted here.
- Customized Correction: Corrected narrative can be further edited here.
- Final Narrative: The final narrative will be generated here.

Note: All the steps (4~8) mentioned before, can be performed with Error Summary table 2 as well.





4.10 Step 10: Reference between Error Summary Table and Error Highlighted

User can <u>cross-reference the errors</u> of summary table with "Error Highlighted" section and **identify which errors are correctly identified by tool**. In "Error Highlighted" section, all the errors are <u>highlighted with some index numbers</u> (subscript, blue color) associated with it, which refers to the row number of Error Summary Table.

<u>Note</u>: In "Error Highlighted" section, date Chronology errors are highlighted in sky blue color and all other errors in yellow color, so that user can distinguish date chronology errors easily.

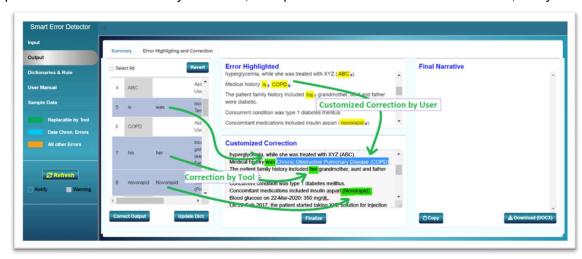


4.11 Step 11: Customized Correction by User

When user clicks on the 'Click to Correct Output' / 'Correct Output' button, the <u>tool corrects</u> the narrative for selected errors, and <u>transfers corrected output to 'Customized Correction' section</u>. User can further edit the narrative or make additional corrections here.

<u>Note</u>: User should <u>edit the non-editable errors</u> (gray color in Error Summary Table) in this "Customized Correction" section, as needed.

If user clicks on "Correct Output" button after performing customized corrections, all those changes will be gone. The newly corrected narrative will be transferred into this section. So, perform all the "Correction by Tool" first, then perform the "Customized corrections", if any.





4.12 Step 12: Finalize Narrative

Once all the corrections are done, user needs to <u>click on "Finalize" button</u> to generate the final narrative. User will then click on "Copy" button to <u>copy the final narrative into clipboard</u>. Or user can also click on "Download (DOCX)" button to <u>download the final narrative</u>.

<u>Note</u>: All the <u>corrections made</u> to original input will be <u>highlighted in green color</u>. If new paragraphs are created in the customized correction section, this highlight feature may not work. But all the changes will be reflected in the final narrative.



Reminder: A common reminder will be shown when user clicks on "Click to Correct Output"/ "Correct Output", "Finalize", "Copy", "Download (DOCX)" buttons. This reminder contains few <u>common instructions related to the Quality Check</u> process. User should go through them at least once.

<u>Final Update Dictionary</u>: If user <u>doesn't select one or more "Spelling Mistake"</u> errors <u>during "Correction by Tool"</u>, then tool <u>prompts user to add those words to dictionary</u> (Pop-up), when "Finalize" button is clicked. User may select one or more words and click on "Update" button in that pop-up, to add them into dictionary. Or user can simply ignore it and click on "Cancel" button. Validation phase will be involved to validate all the words added to dictionary and then final dictionary will be updated.

4.13 Dictionaries & Rule

"Dictionaries & Rule" tab contains two panels:

- 1. Rule: It contains a file describing all the scenarios which are considered by this tool.
- 2. **Dictionaries**: This panel contains an additional dictionary, abbreviation exceptions, Sanofi product list and R3-Unit list.

4.14 User Manual

"User Manual" tab contains a User Manual guide reference (PDF) for this tool. User should follow all the mentioned instructions / guidelines properly.

4.15 Sample Data

"Sample Data" tab contains few sample narrative for the testing/ demo of this tool. User can view or download those sample narratives.



5.0 Instructions for Error Correction

Due to weak connectivity, sometimes, user may face an error with a message "Disconnected from the Server" and his/ her screen will gray-out. In such cases, user should reload/ reopen the tool & use it. If the issue persists, user may contact project POC or reach out to development team for help.

Run-time error exceptions are handled by this tool. If some error happens during tool's processing phase, a pop-up with short error description will be displayed in the browser window. If any such issue occurs, user should take screenshot & report that issue to project POC with reference to the narrative sample & screenshot. Project POC will then inform the development team for investigating that issue.

If user is unable to access the link, reach out to Project POC/ development team to enable the access. Project POC/ development team will raise GSD/ firewall request as per requirement. But before raising this request, user should verify that the VPN connectivity & proxy settings have been set up properly.

6.0 Process Workflow

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7.0 Frequently Asked Questions

FAQ1: Does this tool store any data in the server?

<u>No</u>, this tool doesn't store any information. It simply highlights the error in the loaded narrative and provides suggestions to those errors, wherever applicable. When user refreshes the tool, it creates a new session. No data from narrative are being stored.

FAQ2: Does this tool connect with ARGUS Safety database?

<u>No</u>, user need to copy the narrative from ARGUS and paste into the tool. After performing the necessary changes, user need to copy the final narrative and paste it back into ARGUS. This copypaste is to be done by user. Tool doesn't interact with ARGUS.

FAQ3: Does this tool automatically correct the narrative?

Tool only highlights the errors and suggests, but <u>doesn't correct them automatically</u>. User will have to apply their subjective knowledge and then accept/ reject the errors detected by tool. Based on user's selection, the auto correction will happen. If no errors are accepted, then tool will not correct the narrative. There is also one option to perform additional changes in the "Customized Correction" section of Output tab.

FAQ4: What will happen if user doesn't accept any error suggested by the tool?

Tool will not make any changes in the narrative. The narrative will remain as it is.

FAQ4: Is the tool accessible via Internet?

<u>No</u>. This tool is hosted within Cognizant environment and can only be accessed inside Cognizant network. If you want to access it outside of Cognizant office, use Cognizant RAVPN.



8.0 Change Log

Version Number	Changes Made					
V1.0.0	Initial baseline created on 13-Nov-2020 by MD Amir Sohail					
VX.Y.Z	<please are="" below="" change="" changes="" configuration="" control="" de="" followed="" form="" given="" if="" item="" maintained="" needs="" not="" of="" refer="" separately="" status="" t="" template="" the="" tool=""></please>					
	Section No.	Changed By	Effective Date	Changes Effected		

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