

PP21: Automation of Submission Packages Quality Checks

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ABSTRACT

This paper introduces the tool used at Janssen for automated quality and compliance checking of clinical trial data packages before submission to regulatory agencies. Up until recently, submission packages were manually checked in the form of QC checklists that looked at correctness, completeness and compliance to regulatory guidelines of clinical trial data package attributes. This is a laborious and tedious job, with the possibility of human error. The tool allows the automation of certain parts of these QC checklists and acts as a final gateway check before sending clinical trial data to Janssen's regulatory / publishing group to load onto the eCTD. By automating the checking and delivery of clinical trial data packages, the hand-overs between regulatory/publishing and data management/stat programming departments is also clear without any confusion across different therapeutic areas, functions (DM, STAT) and packages (SDTM, ADaM etc.).

INTRODUCTION

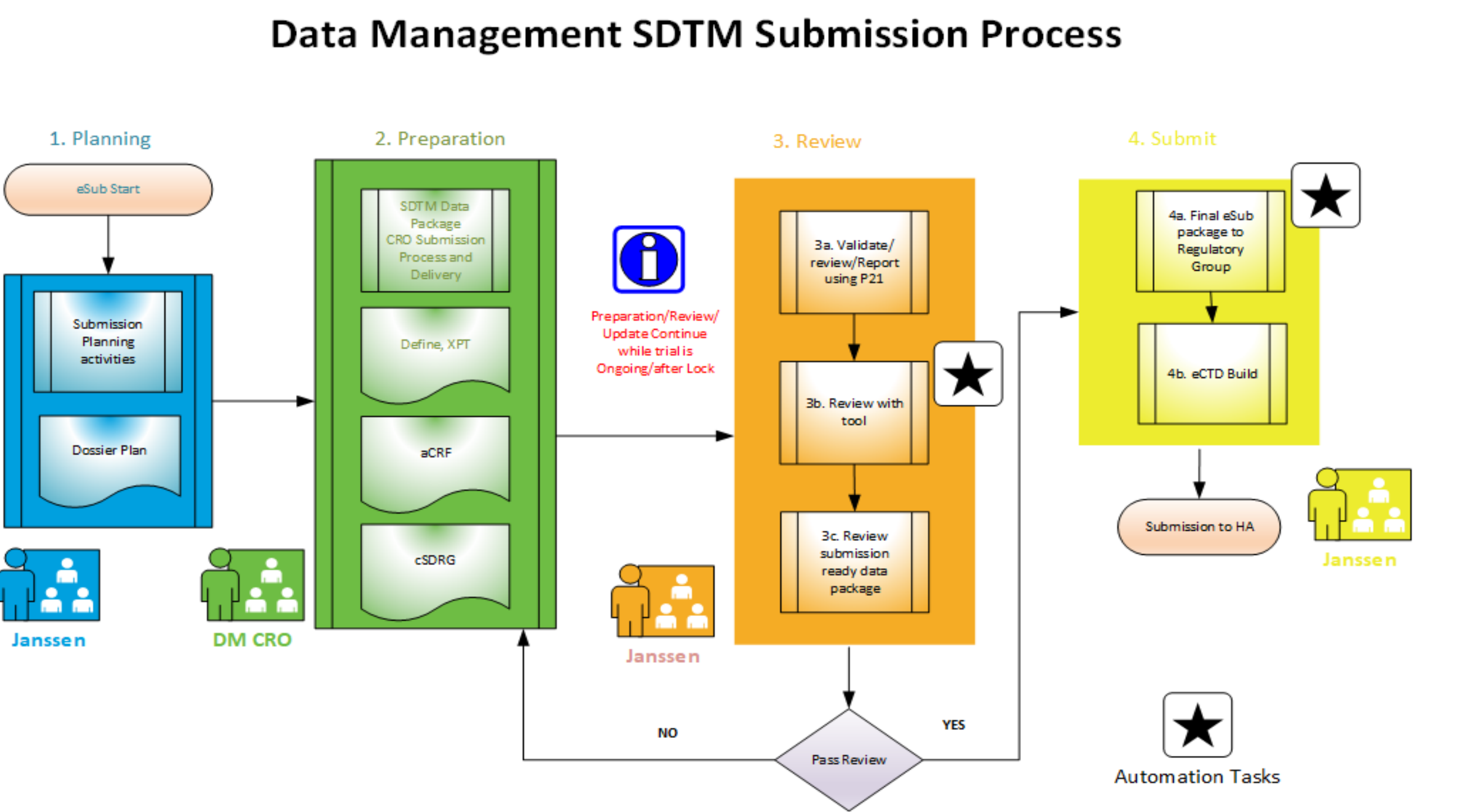
At Janssen, Data Management (DM) activities are outsourced to DM CROs. The DM CROs are contracted to deliver SDTM to Janssen during the trial conduct and to prepare the SDTM submission package after database lock. When the SDTM package is ready for submission to health authorities, there are multiple aspects and attributes that need to be checked, and this was, up until recently, a completely manual process using QC checklists.

Some of these checks are time-consuming, for example checking the hyperlinks and bookmarks in define XML are working and pointing to the correct location, or ensuring that PDF document attributes comply with the latest guidelines from health authorities. This tool automates the items listed in the Janssen QC checklists and submission package compliance can now be verified at the click of a button, reducing human error and time needed for review.

For example, if the submission responsible were to review a submission that includes 68 packages (multiple studies all including SDTM, ADaM, BIMO, etc.), and if each package review takes approximately 4 hours, it would take a total 34 business days to complete the review. This tool can perform the same review in a couple of minutes per package which cuts down the review time significantly. If the package is not submission ready the automated tool will produce a report of errors and halt the delivery to the Janssen regulatory group. The checking can be repeated as many times as needed until the package is submission ready.

Once the package is submission ready and no more errors occur, this tool also automates the delivery of the submission package to the Janssen regulatory group network server for building eCTD. This automation streamlines eCTD folder creation and will also protect the eCTD integrity by disabling the functions to re-update the package in the regulatory server without updating eCTD.

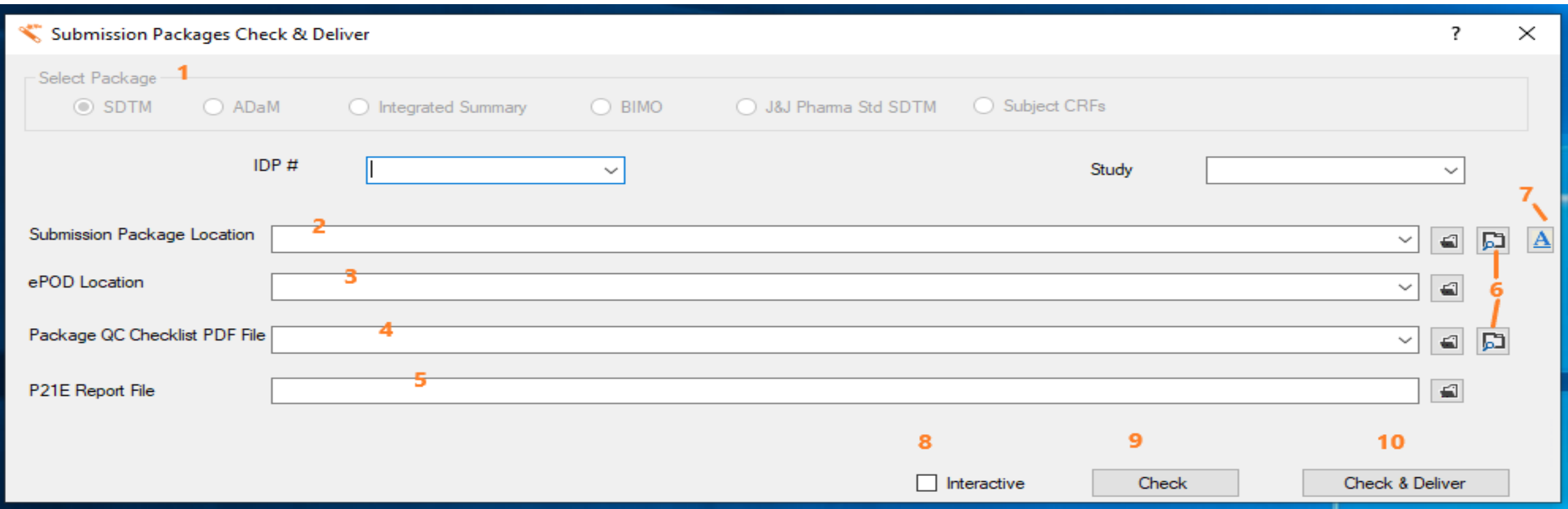
PROCESS



REFERENCES

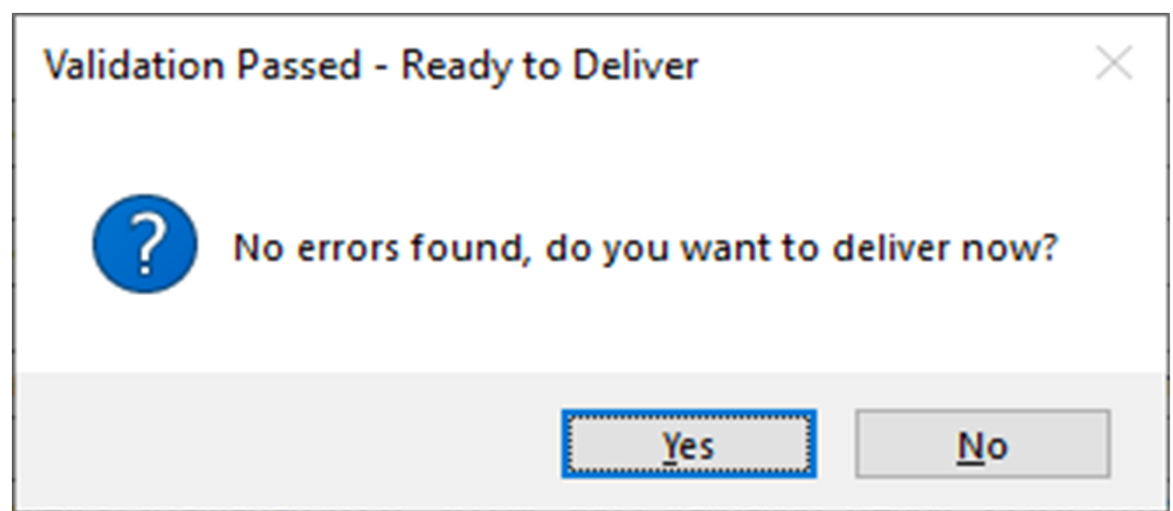
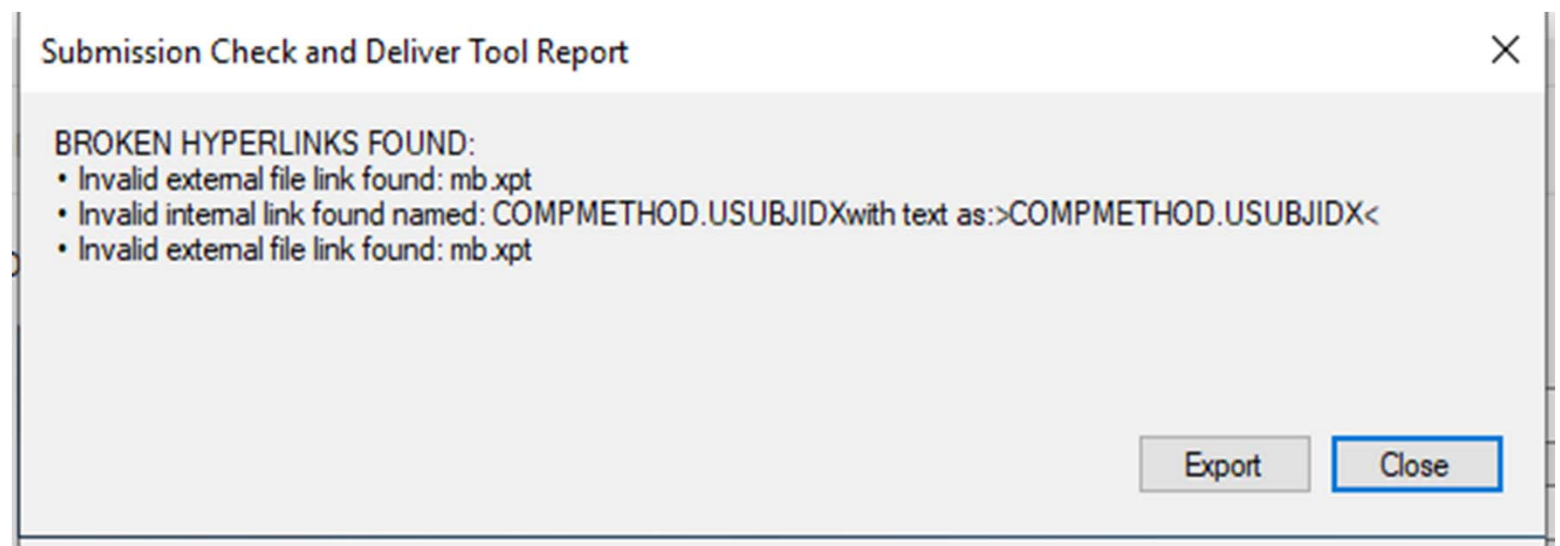
- FDA, Providing Regulatory Submissions In Electronic Format – Standardized Study Data – Guidance for Industry
- FDA, Portable Document Format (PDF) Specifications – Technical Specifications Document – Guidance for Industry
- FDA – Study Data Technical Conformance Guide – Technical Specifications Document – Guidance for Industry
- FDA, Specifications for File Format Types Using eCTD Specifications – Guidance for Industry
- Janssen SDTM Submission Package QC Checklists & Job Aids

PROOF OF CONCEPT



1. Submission package selection
2. Data management clinical data repository package location
3. Regulatory group drop zone location
4. Signed manual QC checklist electronic file
5. CDISC compliance validation report
6. Preview submission package in desktop
7. Check hyperlinks & bookmarks
8. Option to run in batch mode
9. Option to check only without delivering to internal regulatory group
10. Option to check and deliver the package to internal regulatory group

SAMPLE RUNS



Please refer to the accompanying paper Poster PP21: Automation of Submission Packages Quality Checks to see the complete list of checks. Note, this automation tool does not check compliance to CDISC standards.

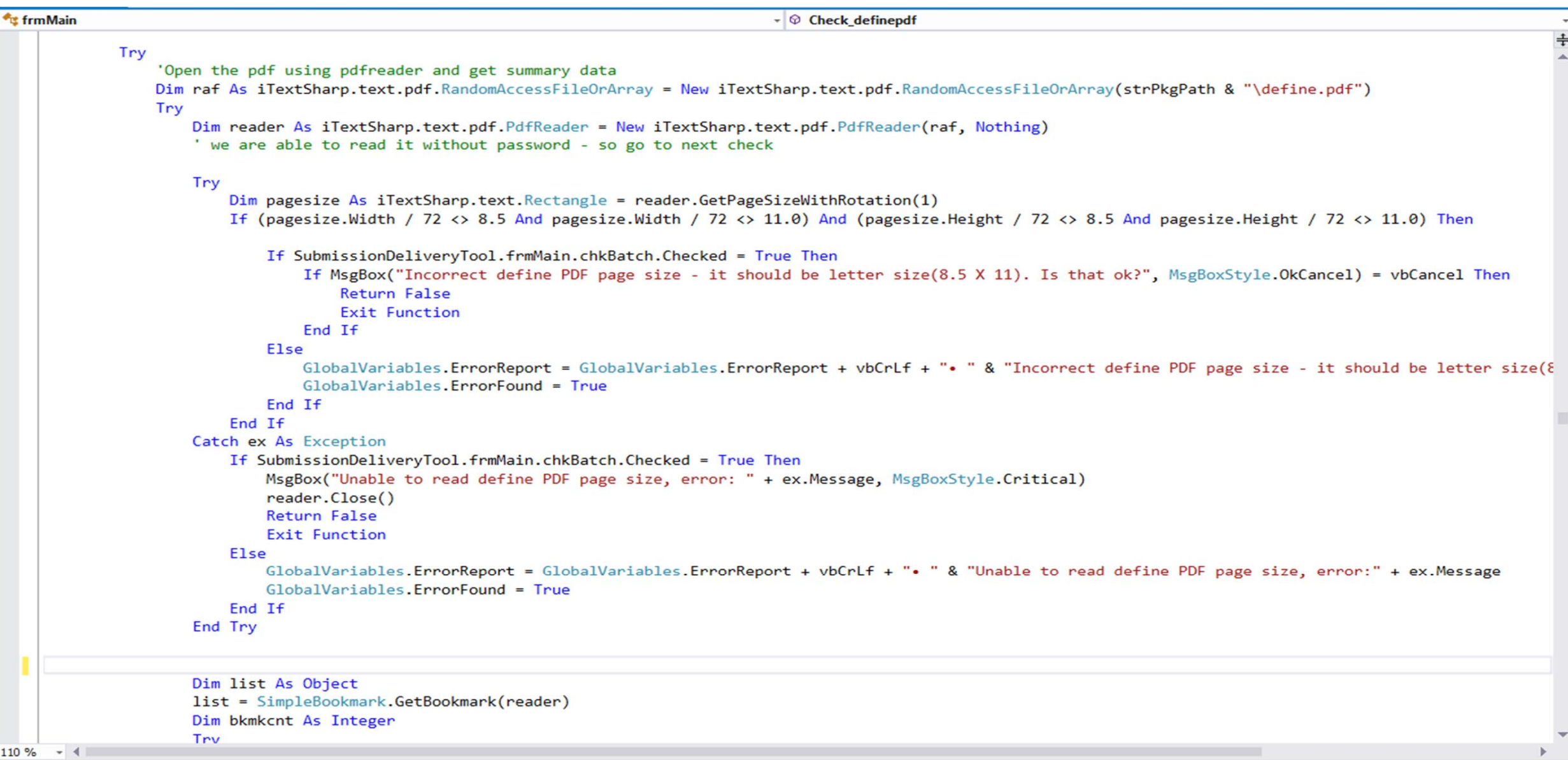
ACKNOWLEDGEMENTS

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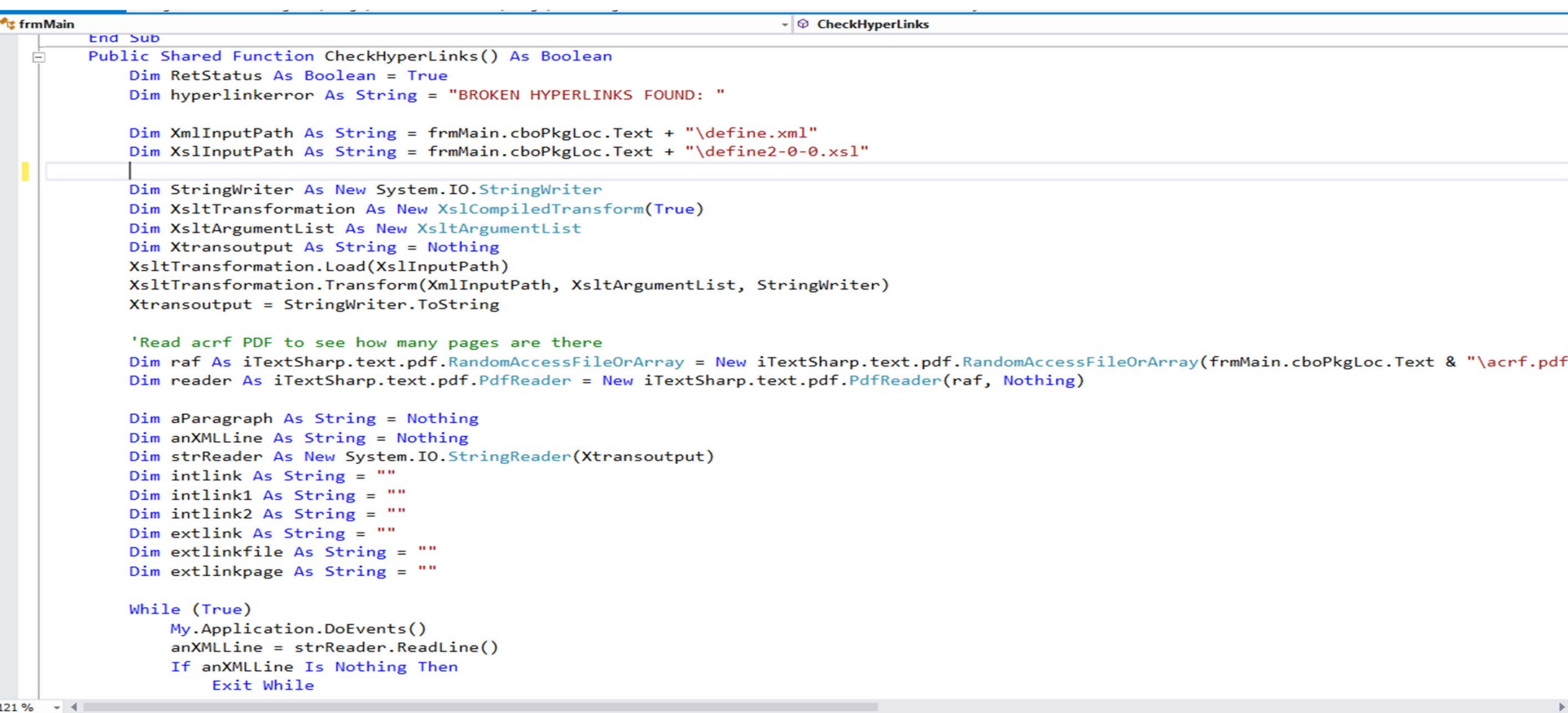
.NET SOURCE CODE

This automation tool can be implemented in any languages that can employ API calls and OS file/system functions, like Python, C#, etc.

Below is a snippet of code used in VB .NET to read PDFs:



Below is a snippet of code to read and check XML file:



CONCLUSION

This proof of concept shows that submission package review can be fully automated, and the sponsor can deliver timely and quality submission packages for faster approval. Other submission packages like Subject CRFs, ADaM, and BIMO can also be added to this automation. Further enhancements are being considered such as adding more challenging checks, PDF hyperlink cognitive checks, and use of Robotic Process Automation (RPA).

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