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Single Day Events

D-pack - Tool to effectively compile m5 structure

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Abstract

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The m5 (Module 5) in the eCTD is an essential framework to display clinical data and results for regulatory submissions. This consistent structure aids in easy navigation for reference and review. However, manual compilation of the folder is arduous, long-drawn and prone to missing key documents.

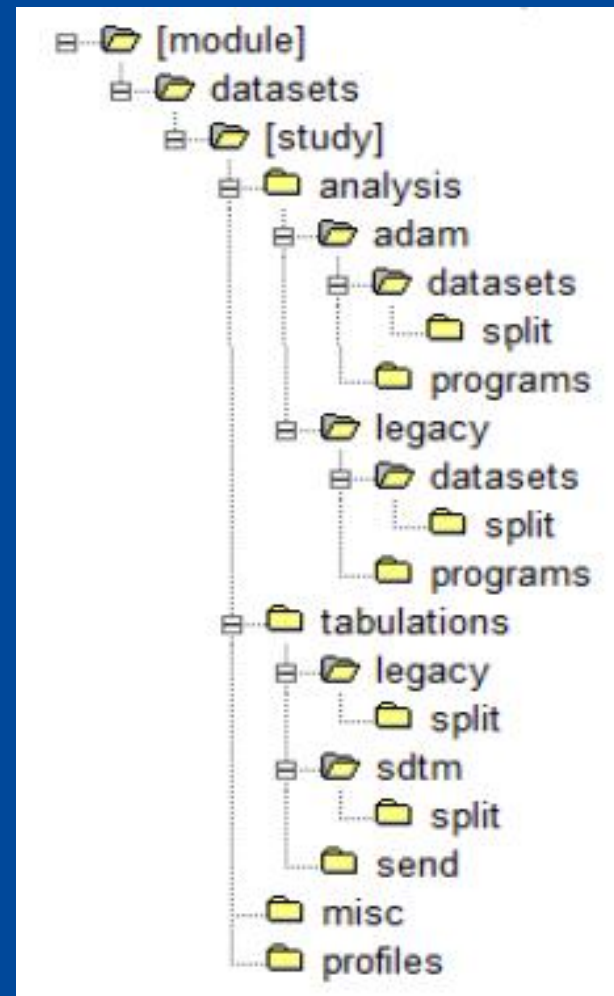
Once the necessary inputs are placed in the study folder, the D-pack tool automates the m5 folder creation and compilation, consisting of SDTM/ADaM/TLFs datasets/outputs, programs, define.xml, reviewer's guidelines, arm, QC documents, protocol, SAP and annotated CRF in their valid standard format as per guidelines. In addition, the tool performs a few checks and throws a warning for missing files, a datetime stamp mismatch and modlog verification for the right Sponsor name and Study ID. This reduces the manual error and time required for putting the files together to a great extent. A detailed walkthrough of the tool's working principle and advantages will be shared at the conference.



Understanding M5

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- Standard structure for regulatory submissions
- Ease in navigation for reference and review
- Aligned with FDA Technical Conformance Guide
- Transparency and clarity of clinical trial data





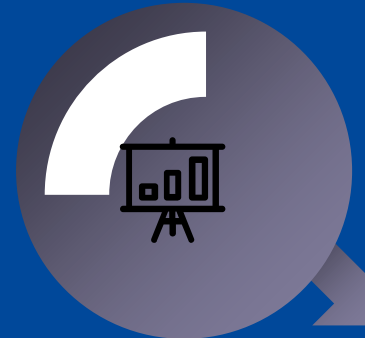
Manual Limitations

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Time

Manually compiling the folder might consume huge time & effort.



Standards Compliance - Compromised

- Missed regulatory requirements
- Absent mandatory subfolders
- Inconsistent naming conventions

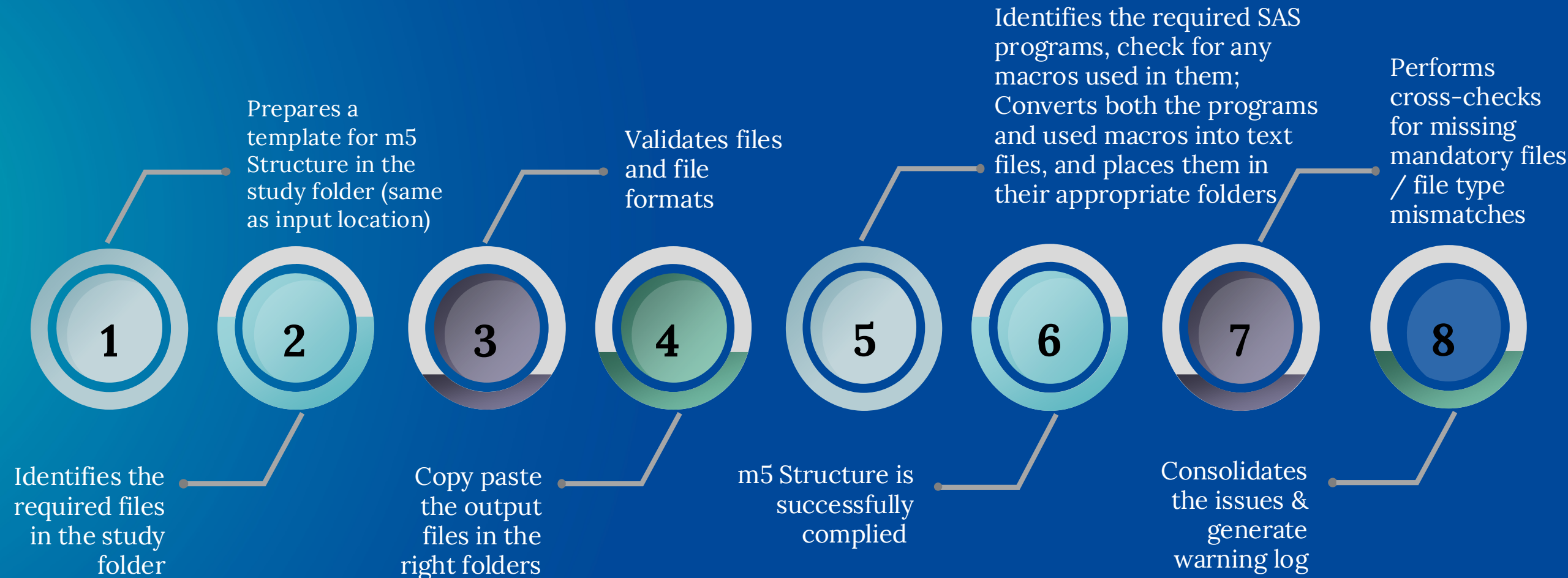


Human Errors

Putting together huge data paves way to misplace or forget to place files in the right folder.



Underlying Workflow





How is it Done

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A screenshot of the Zifo D-Pack web application interface. The interface has a white background with a subtle grid pattern. In the top left corner is the Zifo logo. In the top right corner is the title "D-Pack" in a large, bold, dark green font. Below the title is a light green rounded rectangle containing a form. The form has four sections: "Study Name" with a text input field containing the placeholder "Enter study name"; "Select Input Folder" with a dark green button and a text input field; "Document Keywords (comma separated)" with a text input field containing the placeholder "e.g. sDRG, aDRG"; and "Generate m5" with a dark green button.

Zifo

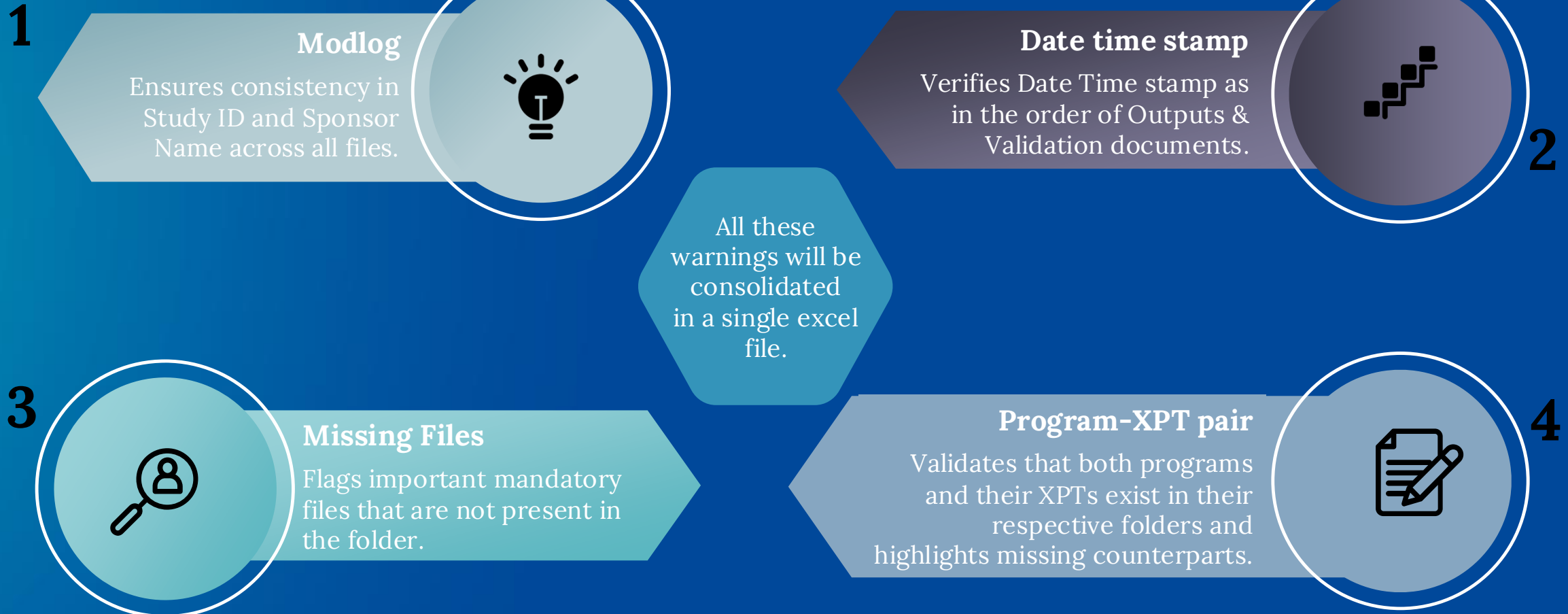
D-Pack

Study Name

Select Input Folder

Document Keywords (comma separated)

Generate m5





Future Enhancements

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01

Split datasets

02

PMDA
Submission

03

Legacy
studies

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