KeyCombine User Guide

1. Introduction

1.1 Overview

Welcome to KeyCombine, your go-to solution for effortlessly generating Combined PDF files from your TLF sources. This software is specifically designed to help the Pharmaceutical Industry with the task of generating Combined TLF reports in PDF format for FDA submissions.

Creating a Combined PDF file with KeyCombine is as simple as drag-and-drop and a click. Say goodbye to messy scripts and non-specialized software; with KeyCombine, you have a tool specifically designed for the task, offering a straightforward process for creating your FDA Submission-ready Combined PDF files. The Combined PDF file generated by KeyCombine is a **US-eCTD v4** compliant PDF file that is ready for FDA Submission.

In this guide, you will find detailed instructions on installation, system requirements, and an overview of the software's capabilities.

1.2 System Requirements

Before installing KeyCombine, ensure your system meets the following requirements. This includes hardware specifications, operating system compatibility, and any additional dependencies.

- Operating System: Windows 10, Windows 11, Windows Server 2016 or higher
- Processor: Intel Core i3 or AMD Ryzen 3 processor or higher
- RAM: 4GB RAM
- Disk Space: Minimum 1GB available disk space required
- Graphics: Integrated graphics card or better

1.3 Installation

To download KeyCombine Desktop, go to the KeyCombine Desktop Download Page and click on **Free Download button**. After Download is complete, follow the steps below:

- Locate the downloaded KeyCombine installer file.
- Double-click the installer file to launch the installation wizard.
- Follow the on-screen instructions to proceed through the installation.
- Choose the installation directory and any additional settings as needed.
- Click "Install" to begin the installation process.
- Once the installation is complete, click "Finish" to exit the wizard.

2. Getting Started

2.1 User Interface Overview

Welcome to the KeyCombine User Interface (UI) overview. This section provides a comprehensive understanding of the various elements and functionalities within the software's graphical interface. The UI is designed to be intuitive, simple, and efficient, ensuring a smooth user experience.

Upon launching KeyCombine, you'll be greeted by the **Main Working Area**. The interface is streamlined, with minimal windows and menus, focusing on simplicity. The Main Working Area is divided into three key zones:

- **Left Pane**
- **Right Metadata Pane**
- **Upper Toolbar**
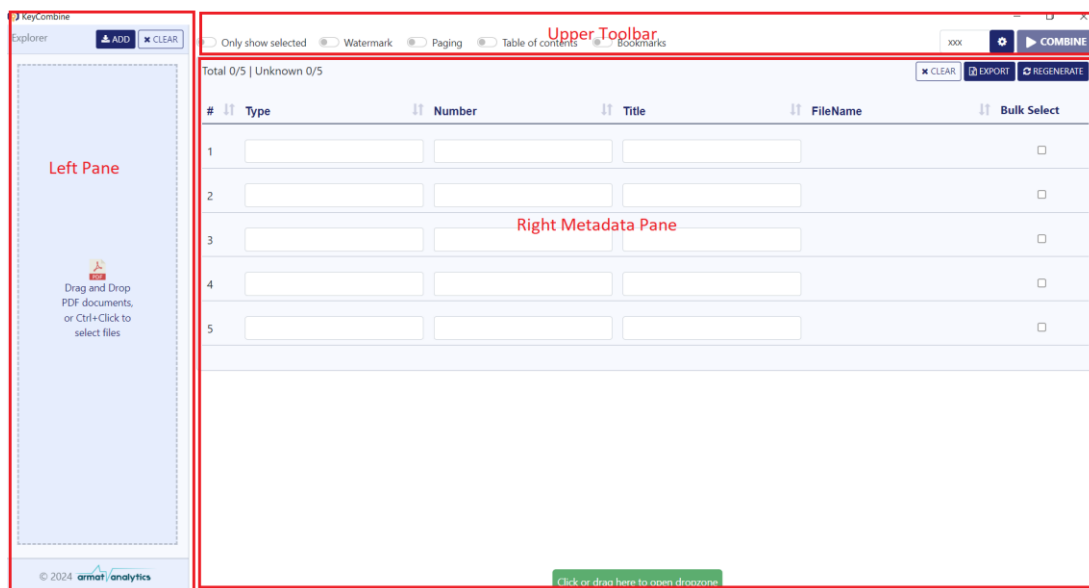
Left Pane

The Left Pane primarily serves as a Drag and Drop zone and file management area for PDF files that must be combined. All functionalities related to dragging and dropping files, as well as deleting them, are discussed in the 3.2 Uploading PDF Files section. Additionally, this pane is used for editing created templates, which will be covered in detail in the **Creating and Managing Templates** section.

Right Metadata Pane

The Right Metadata Pane houses the Files Metadata Table, where you can input key metadata such as TLF Title, Number, Type, and more for each PDF file. This table is essential when generating a Table of Contents (TOC) for the combined PDF file. If your objective is simply to merge the files without a TOC, you can ignore this table. Detailed instructions on using the Metadata Table are provided in the 3.1 Uploading Metadata and 3.3 Working with Metadata Table sections.

Upper Toolbar

The Upper Toolbar contains the main tools used to customize the final combined PDF file. This includes options such as adding a TOC, applying watermarks, setting up pagination, and more. Each option will be discussed in detail in their respective sections.

3. Combine your files. A Step-by-Step guide.

Imagine you've been assigned to create a combined PDF file using a list of Tables, Listings, and Figures (TLFs) that your team has been working on for the past week. You have a folder filled with individual PDF files, each representing a Table, Listing, or Figure. Additionally, you have a spreadsheet that tracks all the TLFs produced by your team.

KeyCombine is the perfect tool for this exact scenario. By using its intuitive interface, you can generate a Combined PDF file in no time by following the steps described in the further sections.

3.1 Uploading Metadata

Note: *If you are using the KeyCombine Desktop tool to simply combine a bunch of PDF files, and you're not interested in generating a Table of Contents, adding Bookmarks, or if the order of the files being combined isn't important to you, you can safely skip this section and go directly to the **3.2 Uploading PDF** Files section.*

The first step is to import the list of TLFs, along with their relevant metadata, into the KeyCombine Desktop app. Don't be intimidated by the term "metadata"—it simply refers to the Title, Number, Type and File Name of each TLF object. This information should be readily available in your spreadsheet, as these are standard and essential details commonly used across the industry.

In order to import all the necessary information, you may need to rearrange your file so that it resembles the format shown below, and then save it as an Excel file.

	A	B	C	D
1	Type	Number	Title	FileName
2	Table	14.1.2	Subject Recruitment by country and center (Full Analysis Set)	DS002
3	Listing	14.1.103	Subject disposition (All Subjects)	DS103
4	Figure	14.1.210	Subject Recruitment by country and center (Full Analysis Set)	DS210

Once you have the metadata file ready, **make sure the Excel file is closed before you upload it to KeyCombine Desktop**. You can then use the drop zone in the bottom center of the Metadata Table Zone to drop your Excel file and upload the information into KeyCombine Desktop.

Drag and Drop Excel template, or Click to select file

Click or drag here to open dropzone
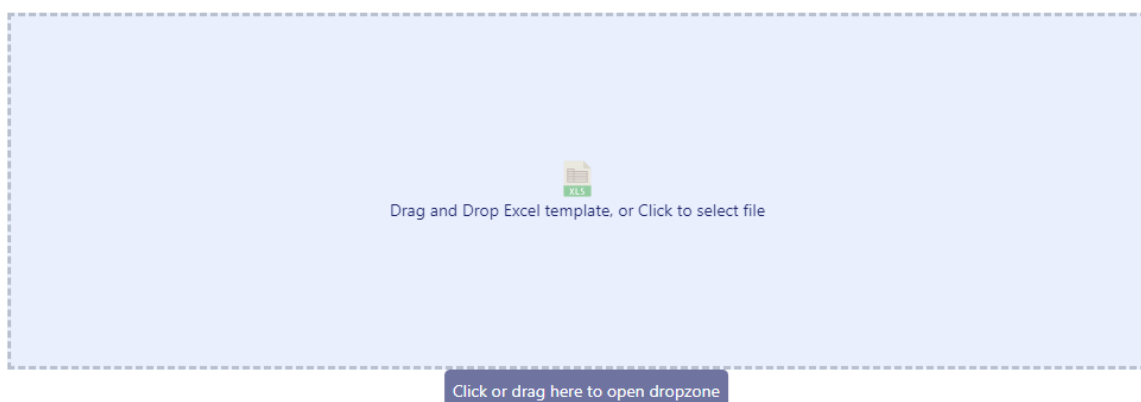
The metadata table will then be populated with the information from your spreadsheet. You can further update titles, adjust the order, and make other modifications to the table as needed.

| Total 0/3 | Table 0/1 | Listing 0/1 | Figure 0/1					**✕ CLEAR** **⬘ EXPORT** **⟳ REGENERATE**
# ⇅	**Type** ⇅	**Number** ⇅	**Title** ⇅	**FileName** ⇅	**Bulk Select** ⇅ ⌄
1	Table	14.1.2	Subject Recruitment by country and	DS002	☐
2	Listing	14.1.103	Subject disposition (All Subjects)	DS103	☐
3	Figure	14.1.210	Subject Recruitment by country and	DS210	☐

In the rightmost column of the metadata table, you'll find checkboxes that let you select or deselect TLF objects for inclusion in the final combined file. This feature will become more intuitive after the PDF files are uploaded.

3.2 Uploading PDF Files

Now that you have uploaded your metadata table and have a structured list of the files you want to combine, the next step is to upload the actual PDF files that will be merged. This can be easily done using the drag-and-drop functionality in the Left Pane.
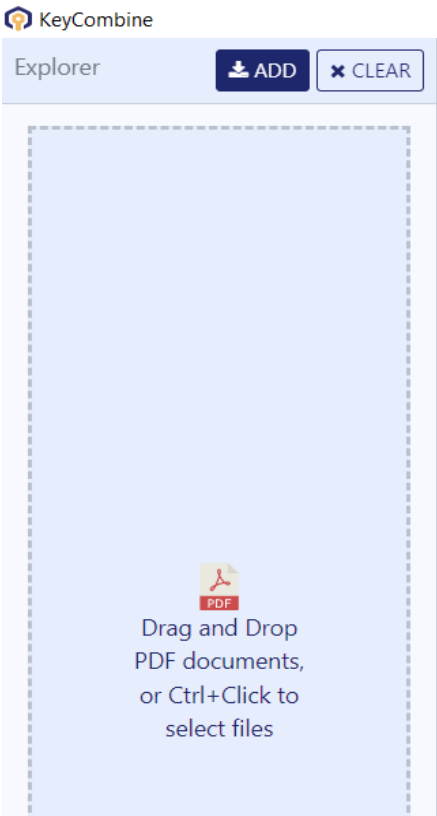
Drag and Drop:
Simply drag your PDF files into the Left Pane. You can select multiple files at once, making the process efficient.
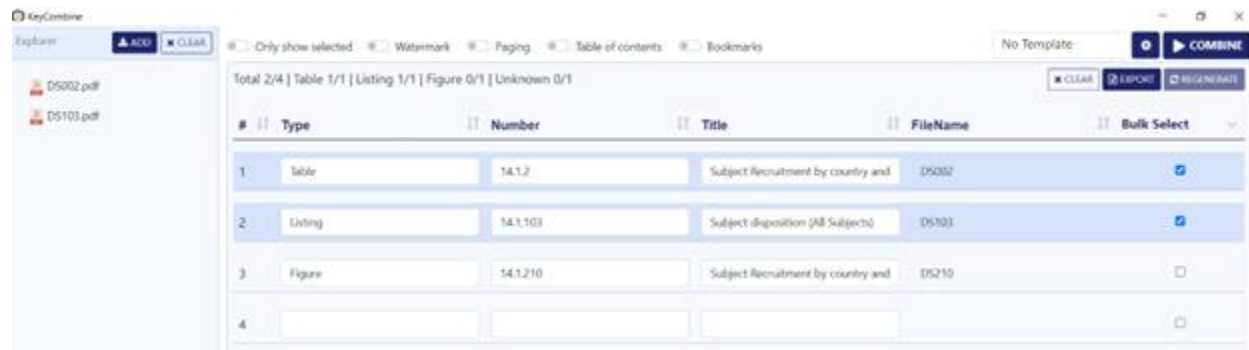
Managing Files:
Once the files are added in bulk, you have several options to manage them:

- **Add Files:** Use the **Add** button at the top of the Left Pane to browse for and add more files, or simply drag and drop additional files into the pane.
- **Clear All Files:** To remove all uploaded files, click the **Clear** button.
- **Delete Individual Files:** To delete a specific file, right-click on it and select the **Remove** option.

Automatic Matching:
Once the files are dropped into the Left Pane, the system will automatically match them with the corresponding entries in the metadata table. For each record in the metadata table that has a matching PDF file, the selection checkbox will be automatically checked. This indicates that these records will be included in the final combined PDF file.

3.3 Working with Metadata Table

The Metadata Table in KeyCombine is a crucial component for organizing and managing the information related to each PDF file that will be included in your final combined document. This section will guide you through the process of interacting with the Metadata Table, ensuring that your final PDF is properly structured and contains all necessary information.

Overview of the Metadata Table

The Metadata Table is located in the Right Pane of the Main Working Area. This table is where you'll input key details for each PDF file, such as Title, Number, and Type. These details are essential when generating a Table of Contents (TOC) for your combined PDF, as they ensure that each section is correctly labeled and ordered.

Adding and Editing Metadata

1. **Automatic Population:**
   When you upload your metadata file (as discussed in Section 3.1 3.1 Uploading Metadata), the Metadata Table will automatically populate with the information from your spreadsheet. This includes details like TLF Title, Number, Type, and File Name.

2. **Manual Entry:**
   If you need to add or edit metadata manually, simply click on the relevant cell in the table. You can enter or update information as needed. For instance, if a title is missing or incorrect, click on the "Title" cell and type the correct information.

Sorting Metadata

You can sort the Metadata Table by any column to organize your files according to Title, Number, Type, or any other field. Simply click on the column header to sort the entries in ascending or descending order.

Selecting Files for Combination

1. **Selection Checkboxes:**
   The rightmost column in the Metadata Table contains checkboxes that allow you to select or deselect files for inclusion in the final combined PDF. By default, files that have a matching PDF uploaded are automatically selected.

2. **Bulk Selection/Deselection:**
   To select or deselect multiple files at once by their type, open the dropdown menu at the top of the Bulk Select column to access filtering options for selecting files. For example, if you want to select only the "Tables," open the dropdown menu in the Bulk Select column header and choose "Tables."

3. **Using the 'Only Show Selected' Switch:**
   After selecting the entries you want to include in the combined PDF, you can use the "Only Show Selected" switch located in the upper toolbar. Activating this switch will filter out all records that do not have the checkbox selected, allowing you to focus only on the entries that will be included in the final document.

Metadata Counter

At the upper left corner of the Metadata Table, you'll find a counter that tracks the number of Tables, Listings, Figures, or Unknown objects that are selected to be combined. This counter updates automatically as you select or deselect files, giving you a quick overview of the content that will be included in the final PDF.

Total 2/4 | Table 1/1 | Listing 1/1 | Figure 0/1 | Unknown 0/1					✖ CLEAR 📄 EXPORT ⟳ REGENERATE
# ⇅ Type	Number ⇅	Title ⇅	FileName ⇅	Bulk Select ⇅	⌄

Clear and Export Buttons

On the upper right side of the Metadata Table, you'll find three important buttons:
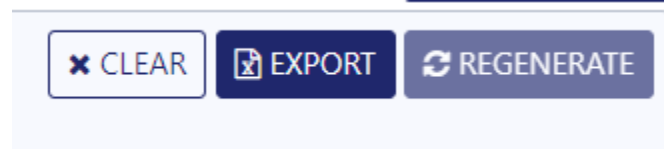
- **Clear:** This button allows you to quickly clear all the entries in the Metadata Table. Use this if you want to start over or make significant changes to the files you're working with.
- **Export:** The Export button lets you save the current state of your Metadata Table, including all selections and entries, as a separate Excel file. This can be useful if you need to revisit or modify the metadata at a later time. You can later upload the exported file to fill in your Metadata Table in a new session.
- **Regenerate:** This button refreshes the Metadata Table based on the current files uploaded in the Left Pane. It becomes active only after using the Clear button, which removes all records from the Metadata Table. Use the Regenerate button to repopulate the table with the latest information from the currently uploaded PDF files.

3.4 Table of Contents

The Table of Contents (TOC) is an essential feature that helps structure your combined PDF document, making it easy for readers to navigate through different sections. In KeyCombine, you can customize the TOC to suit your document's needs using the options provided in the upper toolbar.

1. **Enabling the Table of Contents**
   To include a Table of Contents in your combined PDF file, toggle the **Table of Contents** switch in the toolbar. When enabled, the TOC settings will become active, allowing you to customize various aspects of the TOC.
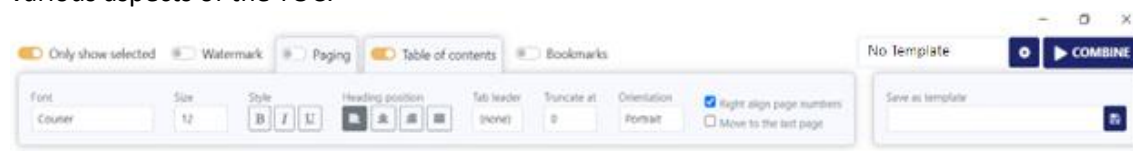
2. **Customizing the Table of Contents**
   - **Font:**
     Select the desired font for the TOC text from the dropdown menu. The available fonts allow you to match the TOC with the rest of your document's style.

- **Size:**
  Use the size option to set the font size for the TOC entries. Adjust the size based on the document's overall typography to ensure consistency.
- **Style:**
  The style options include Bold (B), Italics (I), and Underline (U). You can apply these styles individually or in combination to enhance the TOC's readability and design.
- **Heading Position:**
  Choose the alignment for the TOC headings. The available options allow you to left-align, center-align, or right-align the headings depending on your document's layout requirements.
- **Tab Leader:**
  The Tab Leader option lets you select the style of the leader dots that connect the TOC entries to their respective page numbers. If no leader is desired, you can select "(none)" from the dropdown menu.
- **Truncate at:**
  This setting allows you to control the truncation of long TOC entries. Enter the maximum number of characters that should be displayed before truncation. This feature helps maintain a clean and organized TOC.
- **Orientation:**
  Choose between **Portrait** or **Landscape** orientation for your TOC. This setting determines the layout of the TOC page in the final PDF.
- **Right Align Page Numbers:**
  Check this box if you want the page numbers in the TOC to be right-aligned. This is a common format that improves the visual organization of the TOC.
- **Move to the Last Page:**
  If you prefer to place the TOC at the end of the document rather than at the beginning, check the **Move to the Last Page** box. This option is useful for certain types of reports where the TOC is traditionally placed at the end.

3.5 Adding Bookmarks

Bookmarks in a PDF document are a valuable navigation tool, allowing readers to quickly jump to specific sections of the document. In KeyCombine, adding bookmarks is straightforward and can be done with a simple toggle.

Enabling Bookmarks

To include bookmarks in your combined PDF file, toggle the **Bookmarks** switch in the toolbar. Once enabled, bookmarks will automatically be created based on the metadata and structure of your document.

Once bookmarks are enabled, they will appear in the PDF viewer's sidebar, allowing users to navigate to different sections of the document with a single click.
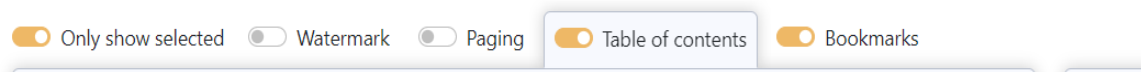
3.6 Adding Paging

Paging is a crucial feature that helps readers navigate your combined PDF document by providing clear and consistent page numbers. In KeyCombine, you can customize the paging settings to fit the specific needs of your document.

1. **Enabling Paging**

   To include page numbers in your combined PDF file, toggle the **Paging** switch in the toolbar. Once enabled, the paging settings will become active, allowing you to customize how the page numbers appear.
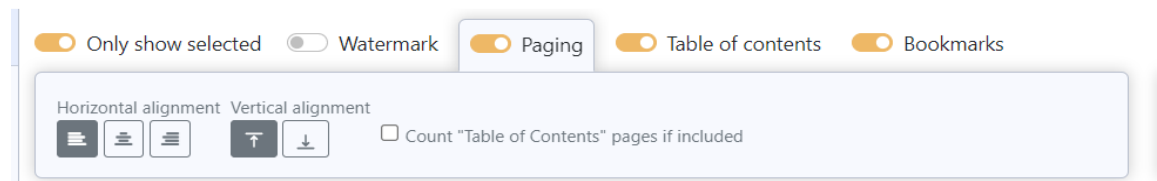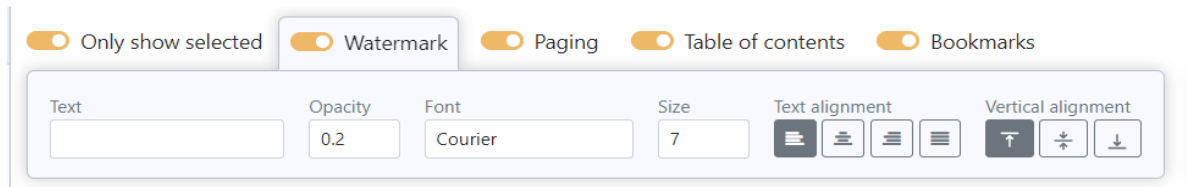

2. **Customizing Paging**

   - **Horizontal Alignment:**
     You can choose the horizontal alignment of the page numbers using the icons in the toolbar. The options allow you to left-align, center-align, or right-align the page numbers at the bottom or top of the page.
   - **Vertical Alignment:**
     Adjust the vertical alignment of the page numbers to position them at the top, middle, or bottom of the page. This setting ensures that the page numbers are placed consistently according to your document's design.
   - **Count "Table of Contents" Pages if Included:**
     If your document includes a Table of Contents (TOC), you can choose whether to include the TOC pages in the page number count. Enabling this option ensures that the page numbers reflect the entire document, including any pages occupied by the TOC.

3.7 Adding Watermarks

Watermarks are a useful feature in PDF documents for branding, confidentiality, or simply for adding a professional touch. In KeyCombine, you can customize watermarks to suit the specific needs of your document.

1. **Enabling Watermarks**
   To add a watermark to your combined PDF file, toggle the **Watermark** switch in the toolbar. Once enabled, the watermark settings will become active, allowing you to customize various aspects of the watermark.

2. **Customizing Watermarks**
   - **Text:**
     Enter the text you want to appear as the watermark in your PDF. This could be a company name, "Confidential," "Draft," or any other relevant message.
   - **Opacity:**
     Adjust the opacity of the watermark using the provided field. The opacity setting controls the transparency of the watermark text, with lower values making it more transparent and higher values making it more opaque. A typical setting might be around 0.2 for a subtle effect.
   - **Font:**
     Choose the font for the watermark text from the dropdown menu. The available fonts allow you to select a style that aligns with the document's overall appearance.
   - **Size:**
     Set the font size for the watermark text. Adjust the size based on how prominent you want the watermark to appear in the document.
   - **Text Alignment:**
     Use the text alignment options to position the watermark text horizontally on the page. You can left-align, center-align, or right-align the text depending on your preference.
   - **Vertical Alignment:**
     Adjust the vertical alignment of the watermark text to position it at the top, middle, or bottom of the page. This ensures that the watermark appears exactly where you want it on each page.

3.8 Using the Combine Button

The Combine button is located at the rightmost end of the upper toolbar. It is easily accessible at any point, allowing you to initiate the merging process as soon as you are ready.
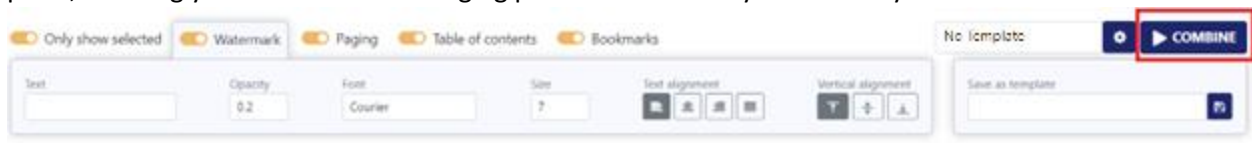

Functionality

- **Immediate Combination:** The Combine button lets you merge all selected PDF files into one combined document. This action can be performed regardless of whether your metadata table is fully set up or if additional settings have been configured.
- **With or Without Metadata:** The flexibility of the Combine button allows you to combine files with or without associated metadata. If metadata has been set up, the combination process will

respect the structure and order defined in the metadata. If no metadata is provided, the files will be combined in the order they appear.

How to Use

- **Ensure Selections:** Before pressing the Combine button, verify that all the necessary files are selected in the Metadata Table (if there is a Metadata table). The files you select will be the ones included in the final combined PDF.
- **Press the Combine Button:** Click the Combine button on the upper toolbar. This action will initiate the merging process. You will see a pop-up window where you need to select the location for the final combined file to be saved. After selecting the location, the file will be created and saved. You will see a pop-up announcing the successful combine operation.
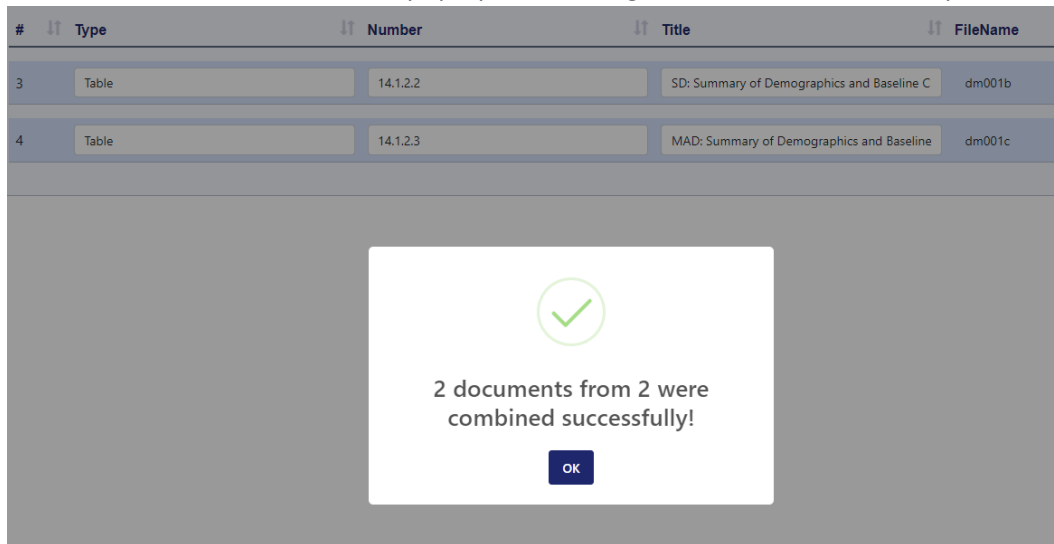
Final Output and Additional Options

Once the process is complete, the system will generate the combined PDF, which you can choose to save in the folder structure. After the output is created and saved, two new buttons will appear next to the Combine button:

- **Open Location:** This button allows you to quickly open the folder where the combined PDF has been saved.

- **Open PDF:** This button allows you to directly open and view the newly created PDF file.
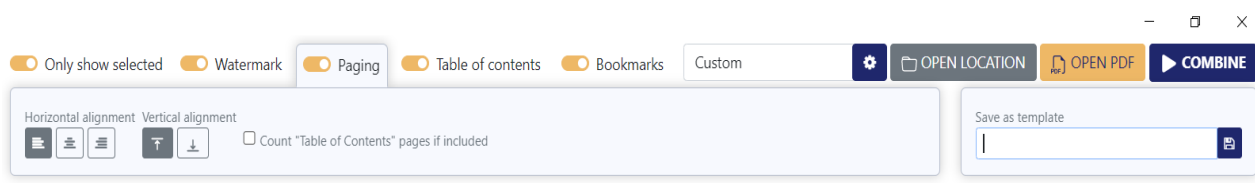
4. Creating and Managing Templates

Templates in KeyCombine provide a way to standardize the settings for various document elements such as Table of Contents (TOC), bookmarks, paging, and watermarks. By saving these settings as a template, you can easily reuse them or share them with others to ensure consistency across multiple documents.

4.1 Creating and Saving Templates

Once you have customized the settings for TOC, bookmarks, paging, and watermarks, you can save these configurations as a template. This template will be stored as a JSON file, which can be used later or shared with others.
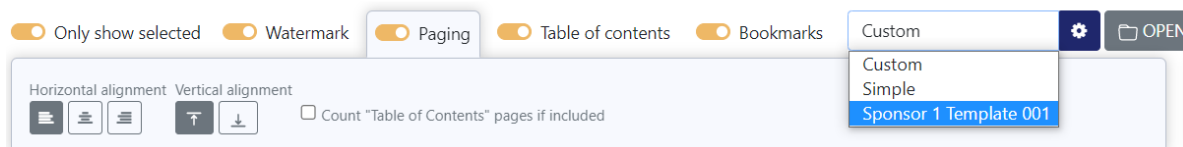
Save as Template:
After configuring your settings, use the "Save as template" option in the interface . This saves all the selected options into a JSON file, which can be accessed and reused in future sessions.
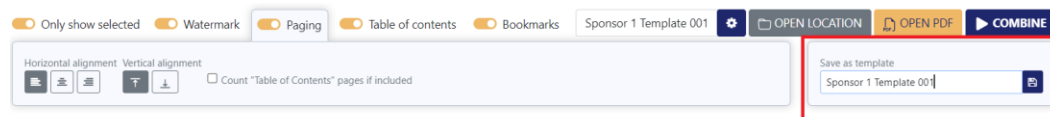
4.2 Using Templates

Once a template is saved, it will be available for selection in the **Templates** drop down menu. Selecting a template will automatically apply the saved settings, ensuring that your document adheres to the pre-configured formatting rules.


4.3 Managing Templates

Templates that have already been created can be viewed, edited, or updated:

- **Viewing and Editing Templates:**
  Click on the gear icon next to the Templates dropdown menu to open the detailed template management interface in the Left Pane. This interface allows you to review the settings saved in each template, make adjustments, and save the updated version.
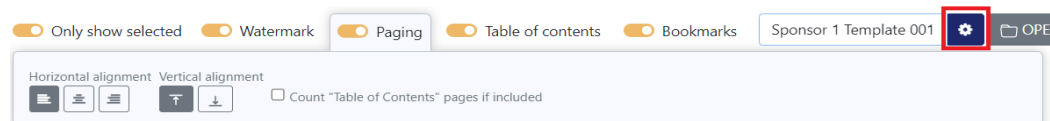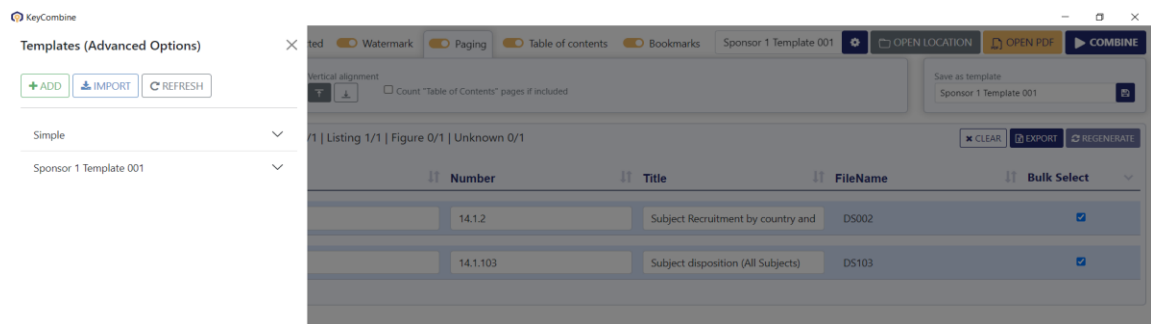
- **Advanced Template Options:**
  In the template management interface, you can add new templates, import existing ones, or refresh the list of available templates. These options help you maintain an organized and up-to-date set of templates for all your document needs.
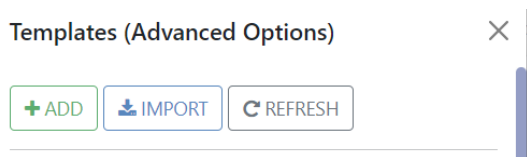
4.4 Sharing Templates

The template JSON files can be shared with colleagues or other users. This feature is particularly useful in environments where a company or client-level formatting policy needs to be maintained. A designated person can create the template and distribute it to others, minimizing the risk of inconsistencies or errors in formatting.

To access the newly created JSON file in your file explorer, use "Open Location" button under the Template Management interface (discussed in **Section 4.3 Managing Templates**). To see the button, click on the Template name and scroll to the very button of the menu.
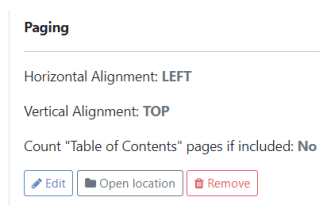
To import the shared template, use the **Import** button under the Template Management interface (discussed in **Section 4.3 Managing Templates**). After clicking on it, simply find the template in the file browser and click **OK**. The template will be added and become accessible for use.

4.5 Templates and CLI Integration

Creating templates is particularly useful when using KeyCombine CLI(Command Line Interface). The settings defined in a template can be referenced through the command line, allowing you to apply the saved configurations directly from the CLI. This integration simplifies the process of applying complex settings and ensures consistency across documents generated via the CLI. For further details on how to use templates through CLI, refer to the **Command Line Interface (CLI) Operations** section.

5. Command Line Interface (CLI) Operations

KeyCombine also offers a powerful Command Line Interface (CLI) that allows users to automate and streamline the PDF merging process. This section provides an overview of how to use the CLI, including its features, commands, and examples.

5.1 Overview

The KeyCombine CLI is a command-line application that enables users to combine PDF documents either through a simple merge or by utilizing an Excel metadata file. The CLI also supports additional features such as generating a Table of Contents (TOC), adding bookmarks, applying watermarks, and enabling paging.

5.2 Features

- **Simple PDF Merging:** Combine multiple PDF files into a single document without requiring additional settings.
- **Combine Using Metadata:** Combine PDF files based on the information provided in an Excel metadata file.
- **Table of Contents Generation:** Automatically create a TOC for the combined document.
- **Bookmark Generation:** Add bookmarks to the PDF for easy navigation.
- **Watermark Support:** Apply a watermark to each page of the combined document.
- **Paging Support:** Include page numbers in the final PDF.

5.3 Using JSON Template Files for Custom Features

To enable custom features such as paging, bookmarks, TOC, and watermarks, you must reference an JSON template file. This JSON template file (discussed in section 4.2 Using Templates) defines the settings for these features and can be created using the KeyCombine Desktop Interface. For specifics on how to create and manage these templates, refer to the **4.2 Using** Templates section of this guide.

5.4 Usage

To use the KeyCombine CLI, you need to add the KeyCombine installation path to the Windows PATH environment variable:

Add keycombine **"..\installation\path\resources\bin"** to Windows PATH environment variable.

You can then execute the CLI using the following command structure:

```
$ keycombine [OPTIONS]
```

5.5 Available Commands and Options

- **-h, --help**: Prints help information.
- **-v, --version**: Prints version information.
- **-d, --pdf-directory**: Specifies the path to the directory containing the PDF documents.
- **-m, --metadata-file**: Specifies the path to the Excel metadata file.
- **-s, --settings**: Specifies the path to the JSON template file with predefined configurations.

- **-o, --output**: Specifies the output path for the combined document.
- **--paging**: Enables paging in the final document.
- **--watermark**: Adds a watermark to the combined document.
- **--bookmarks**: Generates bookmarks for the document.
- **--toc**: Generates a Table of Contents for the document.

5.6 Examples

Simple Merge:

To merge PDF files from a directory into a single document:

```
$ keycombine --pdf-directory "..\path\to\pdf_documents" --output
"..\path\to\combined_doc.pdf"
```

Merge Using Metadata:

To merge PDF files based on an Excel metadata file:

```
$ keycombine --pdf-directory "..\path\to\pdf_documents" --output
"..\path\to\combined_doc.pdf" --metadata-file "..\path\to\tracker_example.xlsx"
```

Generate TOC and Bookmarks:

To include a Table of Contents and bookmarks in the merged PDF:

```
$ keycombine --pdf-directory "..\path\to\pdf_documents" --output
"..\path\to\combined_doc.pdf" --metadata-file "..\path\to\tracker_example.xlsx" --settings
"..\path\to\settings.xml" --toc --bookmarks
```

Include Paging and Watermark:

To add paging and a watermark to the combined PDF:

```
$ keycombine --pdf-directory "..\path\to\pdf_documents" --output
"..\path\to\combined_doc.pdf" --metadata-file "..\path\to\tracker_example.xlsx" --settings
"..\path\to\settings.xml" --toc --bookmarks --paging --watermark
```